

EXHIBIT B

1 IN THE UNITED STATES DISTRICT COURT
 FOR THE DISTRICT OF NEW JERSEY

2 - - -

3 IN RE: VALSARTAN, : MDL NO. 2875
 LOSARTAN, AND :
 4 IRBESARTAN PRODUCTS : HON. ROBERT
 LIABILITY LITIGATION : B. KUGLER

5 _____ :

6 THIS DOCUMENT APPLIES :
 TO ALL CASES :

7

- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

9

10 September 30, 2021

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Videotaped remote deposition of JON P. FRYZEK, Ph.D., taken pursuant to notice, was held via Zoom Videoconference, beginning at 9:01 a.m., EST, on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

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19

20 GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
21 deps@golkow.com

22

23

24

Page 2

1 ZOOM APPEARANCES:
 2
 3 HOLLIS LAW FIRM, PA
 4 BY: BRETT VAUGHN, ESQ.
 5 IRIS SIMPSON, ESQ.
 6 8101 College Boulevard, Suite 260
 7 Overland Park, Kansas 66210
 8 (913) 385-5400
 9 brett@hollislawfirm.com
 10 iris@hollislawfirm.com
 11 Representing the Plaintiffs
 12
 13 DUANE MORRIS, LLP
 14 BY: FREDERICK R. BALL, ESQ.
 15 100 High Street, Suite 2400
 16 Boston, Massachusetts 02110
 17 (857) 488-4229
 18 frball@duanemorris.com
 19
 20 - and -
 21
 22 DUANE MORRIS, LLP
 23 BY: COLEEN W. HILL, ESQ.
 24 30 South 17th Street
 Philadelphia, PA 19103
 (215) 979-1164
 cwhill@duanemorris.com
 Representing the Defendants, Zhejiang
 Huahai Pharmaceutical Co., Ltd., Princeton
 Pharmaceutical Inc., Huahai U.S., Inc.,
 and Solco Healthcare US, LLC
 WALSH PIZZI O'REILLY FALANGA LLP
 BY: CHRISTINE I. GANNON, ESQ.
 Three Gateway Center
 100 Mulberry Street, 15th Floor
 Newark, New Jersey 07102
 (973) 757-1017
 cgannon@walsh.law
 Representing the Defendants, Teva
 Pharmaceutical Industries, Ltd., Teva
 Pharmaceuticals USA, Inc., Actavis LLC,
 and Actavis Pharma, Inc.

Page 4

1 ZOOM APPEARANCES: (Cont'd.)
 2
 3
 4 FALKENBERG IVES, LLP
 5 BY: MEGAN A. ZMICK, ESQ.
 6 230 W. Monroe Street, Suite 2220
 7 Chicago, IL 60606
 8 (312) 566.4808
 9 Maz@falkenbergives.com
 10 Representing the Defendant, Humana
 11
 12 BUCHANAN INGERSOLL ROONEY P.C.
 13 BY: ASHLEY D.N. JONES, ESQ.
 14 1700 K Street, NW
 15 Washington, D.C. 20006
 16 (202) 452-7318
 17 Ashley.jones@bipc.com
 18 Representing the Defendant, Albertson's
 19 LLC
 20
 21 ALSO PRESENT:
 22
 23 VIDEOTAPE TECHNICIAN:
 24 Bill Geigert
 LITIGATION TECHNICIAN:
 Tyler Crotty
 Melisha Valenzuela - Paralegal
 (Hollis Firm)

Page 3

1 ZOOM APPEARANCES: (Cont'd.)
 2
 3 HINSHAW & CULBERTSON, LLP
 4 BY: GEOFFREY M. COAN, ESQ.
 5 53 State Street, 27th Floor
 6 Boston, Massachusetts 02109
 7 (617) 213-7047
 8 gcoan@hinshawlaw.com
 9 Representing the Defendant, ScieGen
 10 Pharmaceuticals, Inc.
 11
 12 BARNES & THORNBURG, LLP
 13 BY: KARA KAPKE, ESQ.
 14 11 S. Meridian Street
 15 Indianapolis, Indiana 46204
 16 (317) 231-6491
 17 kara.kapke@btlaw.com
 18 Representing CVS Pharmacy, Inc., and Rite
 19 Aid Corporation
 20
 21 PIETRAGALLO GORDON ALFANO BOSICK &
 22 RASPANTI, LLP
 23 BY: JASON M. REEFER, ESQ.
 24 One Oxford Centre, 38th Floor
 Pittsburgh, Pennsylvania 15219
 (412) 263-1840
 jmr@pietragallos.com
 Representing the Defendant, Mylan
 Pharmaceuticals, Inc.
 CIPRIANI & WERNER, P.C.
 BY: JILL H. FERTEL, ESQ.
 450 Sentry Parkway, Suite 200
 Blue Bell, Pennsylvania 19422
 (610) 567-0700
 jfertel@c-wlaw.com
 Representing the Defendants, Aurobindo
 Pharma, USA, Inc. and Aurolife Pharma,
 LLC

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Testimony of:
 JON P. FRYZEK, Ph.D.
 By Mr. Vaughn 13

- - -
 E X H I B I T S
 - - -

NO.	DESCRIPTION	PAGE
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Fryzek-7	April 2018 article Indirect treatment comparison of cabazitaxel for patients with metastatic castrate-resistant prostate cancer who have been previously treated with a docetaxel-containing regimen	49
Fryzek-8	US map of ToxStrategies locations	63
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Fryzek-10	Toxic Torts and Environmental Law Defense Practice Seminar Course Materials	86
Fryzek-11	"Epigenetics in chemical-induced genotoxic carcinogenesis" G.A. Chappell, J.E. Rager	145

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Fryzek-12	1990 article Role of metabolism in dimethylnitrosamine induced immunosuppression: A review	154
Fryzek-13	Concise International Chemical Assessment Document 38	161
Fryzek-14	2005 article A cohort study of Parkinson's Disease and Other Neurodegenerative Disorders of Danish Welders	166
Fryzek-15	Evidentiary Order in re: Welding Fume Products Liability Litigation	172
Fryzek-16	2006 article Parkinson's disease and other basal ganglia or movement disorders in a large nationwide cohort of Swedish welders	177
Fryzek-17	September 12, 2008 New Jersey Law Journal	181

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NO.	DESCRIPTION	PAGE
Fryzek-18	2003 article An introduction to power and sample size estimation	190
Fryzek-19	2004 article Cancer risk among statin users: A population-based cohort study	193
Fryzek-20	American Statistical Association News, March 7, 2016 article on statistical significance and P-values	202
Fryzek-21	2013 article Childhood Cancer Incidence in Pennsylvania Counties in Relation to Living in counties with Hydraulic Fracturing Sites	208
Fryzek-22	2013 Letter to the Editor Obfuscation does not provide comfort: Response to the Fryzek et al on Hydraulic Fracturing and Childhood Cancer	213

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EXHIBITS (Cont'd.)		
NO.	DESCRIPTION	PAGE
Fryzek-23	Office of the Attorney General, Commonwealth of Pennsylvania, Report 1 of the 43rd Statewide Investigating Grand Jury	216
Fryzek-24	2002 article The Reliability of Dietary Data for Self- and Next-of-Kin Respondents	227
Fryzek-25	2021 article N-Nitrosodimethylamine Contaminated Valsartan and the Risk of Cancer	292
Fryzek-26	"Benefit-risk Analysis for foods (BRAFO): Evaluation of exposure to dietary nitrates Wikoff, D.S., C.T., J.R., G.C., S.F., C.D.	320
Fryzek-27	2010 article Use of electronic medical records in oncology outcomes research	362

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5	NO.	DESCRIPTION	PAGE
6	Fryzek-28	2012 article	370
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13		Inhalation cancer	
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21		The association	
22		between selected risk	
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2	DEPOSITION SUPPORT INDEX	
3	- - -	
4		
5	Direction to Witness Not to Answer	
6	PAGE LINE	
7	None.	
8	Request for Production of Documents	
9	PAGE LINE	
10	None.	
11	Stipulations	
12	PAGE LINE	
13	None.	
14	Questions Marked	
15	PAGE LINE	
16	None.	
17		
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1 - - -

2 THE VIDEOGRAPHER: Good

3 morning.

4 We are now on the record.

5 My name is Bill Geigert, I'm

6 a videographer for Golkow

7 Litigation Services.

8 Today's date is

9 September 30th, 2021, and the time

10 is 9:01 a.m.

11 This remote video deposition

12 is being held in the matter of

13 valsartan, losartan, and

14 irbesartan products liability

15 litigation, in the United States

16 District Court for the District of

17 New Jersey.

18 The deponent is Jon P.

19 Fryzek, Ph.D.

20 All parties to this

21 deposition are appearing remotely

22 and have agreed to the witness

23 being sworn in remotely.

24 Due to the nature of remote

Page 13

1 reporting, please pause briefly

2 before speaking to ensure all

3 parties are heard completely.

4 All counsel will be noted on

5 the stenographic record.

6 The court reporter is

7 Michelle Gray and she will now

8 swear in the witness.

9 - - -

10 ... JON P. FRYZEK, Ph.D.,

11 having been first duly sworn, was

12 examined and testified as follows:

13 - - -

14 EXAMINATION

15 - - -

16 BY MR. VAUGHN:

17 Q. Dr. Fryzek, how many times

18 have you had your deposition taken

19 previously?

20 A. I think I sent you that

21 list. I can't recall off the top of my

22 head.

23 Q. You sent the last four

24 years. Do you know how many you have in

Page 14

1 your history?

2 A. Oh, prior to that maybe once

3 or twice. Not much.

4 Q. Okay. Do you know the

5 ground rules of depositions pretty well?

6 A. You can repeat them for me.

7 Thank you.

8 Q. So I'll try not to talk over

9 you. You try not to talk over me. If

10 you have any questions or any more

11 clarity on one of my questions, just let

12 me know, and try and give verbal answers

13 instead of head shakes, if that's okay.

14 A. Yeah.

15 Q. Have you ever done a

16 deposition by Zoom before?

17 A. Yes.

18 Q. When was that?

19 A. I believe it was last week.

20 Q. What litigation was that

21 for?

22 A. Let me see if I can

23 remember. I think it was for opioids,

24 Endo Pharmaceuticals.

Page 15

1 Q. And is anyone else in the

2 room with you today?

3 A. No.

4 Q. Do you have any other

5 applications besides Zoom open on your

6 computer?

7 A. I have the Google Chrome for

8 the marked exhibits.

9 Q. Great. No communication

10 devices or apps going on?

11 A. No.

12 Q. And I ask that it stays that

13 way throughout the deposition.

14 A. Okay.

15 Q. And you're not on any

16 medications that would impact your

17 memory, correct?

18 A. Correct.

19 Q. And you don't have any

20 psychiatric conditions that would inhibit

21 you from telling the truth?

22 A. I don't.

23 Q. Are there any errors or

24 corrections that you want to make in your

Page 16

1 report before we get started?

2 A. Not at this time.

3 MR. VAUGHN: Tyler, can we

4 start with Fryzek expert report.

5 (Document Marked for

6 identification as Exhibit

7 Fryzek-1.)

8 THE WITNESS: I have to move

9 this to my other screen so I can

10 see it.

11 MR. VAUGHN: All right.

12 TRIAL TECH: Do you want to

13 mark this as Exhibit 1?

14 MR. VAUGHN: Yeah. If you

15 can keep track of the exhibit

16 numbers, that will be awesome.

17 TRIAL TECH: Absolutely.

18 THE WITNESS: I also have a

19 copy of my report printed out

20 here, so.

21 BY MR. VAUGHN:

22 Q. As long as it's the same, if

23 that's easier for you, feel free.

24 A. Yeah, it's the same.

Page 17

1 MR. VAUGHN: Okay. And then

2 Tyler, can you go to Page 3.

3 MR. BALL: Hey, Brad, it's

4 not showing up in the marked

5 exhibits. Try refreshing.

6 TRIAL TECH: Counsel, I have

7 to -- I have to add it in manually

8 every time it's marked. So you

9 have to give me a few seconds to

10 add it in after it's marked on the

11 record. And then you refresh your

12 screen, and it will flow --

13 populate into the folder.

14 MR. BALL: Got it. Okay.

15 Thank you. I had done that, but

16 apparently I refreshed too soon.

17 TRIAL TECH: Yes.

18 BY MR. VAUGHN:

19 Q. Dr. Fryzek, how much is

20 EpidStrategies being paid per hour for

21 your work?

22 A. \$412.

23 MR. VAUGHN: Tyler, can we

24 go to the Fryzek expert report,

Page 18

1 Appendix C now. And Page 2.
2 (Document marked for
3 identification as Exhibit
4 Fryzek-2.)
5 BY MR. VAUGHN:
6 Q. And then your fee schedule
7 is \$622 an hour, correct?
8 A. I'm not sure where this is
9 from.
10 Q. This is what you produced to
11 us with your expert report. It's Exhibit
12 C of your expert report?
13 A. If it's -- if I produced it,
14 then it's something that my admin put
15 together. So I believe that's true.
16 Q. Okay. So are you paid \$622
17 and then EpidStrat is also paid \$412 for
18 your work?
19 A. No, I'm just paid a regular
20 salary. So this is not outside my
21 salary.
22 Q. Say that again.
23 A. This isn't outside my
24 regular salary. I'm just paid a regular

Page 19

1 salary.
2 Q. So who's being paid the 612?
3 Or 622, I'm sorry.
4 A. I'm not sure. I haven't
5 seen this before. I don't know.
6 Q. So you are not aware of how
7 much you're billing?
8 A. I'm billing what I wrote at
9 first. 415.
10 Q. So the 412 is the proper
11 amount?
12 A. Yeah.
13 Q. And you're positive about
14 that?
15 A. It is. That's my billing
16 rate.
17 THE COURT REPORTER: Doctor,
18 if you can keep your voice up.
19 You're trailing off.
20 THE WITNESS: Okay. Sorry.
21 MR. VAUGHN: Okay. Tyler,
22 can we now go to -- see what it
23 was called -- Jon Fryzek invoices
24 IMS.

Page 20

1 (Document marked for
2 identification as Exhibit
3 Fryzek-3.)
4 BY MR. VAUGHN:
5 Q. Dr. Fryzek, do you have an
6 estimate for how many hours you spent on
7 your expert report?
8 A. No, I have no idea.
9 Q. All right. What is your
10 hourly rate being billed out here?
11 A. Looks like 622. So that
12 must be. That explains it. That must be
13 what IMS is getting. 622 and then they
14 pay us the 415. So that's --
15 Q. And who is IMS?
16 A. It's a firm that hires
17 expert witnesses or finds expert
18 witnesses. This is the first time I've
19 ever worked with them. I never heard of
20 them before.
21 MR. VAUGHN: All right.
22 Tyler, can we now go to Appendix A
23 of his expert report. Fryzek's
24 expert report, Appendix A.

Page 21

1 Can we go to the next page.
2 (Document Marked for
3 identification as Exhibit
4 Fryzek-4.)
5 BY MR. VAUGHN:
6 Q. And I notice you list from
7 2000 to 2006 you were an assistant
8 professor at Vanderbilt. What all did
9 that entail?
10 A. I did research projects with
11 them, and I lectured a couple times.
12 Q. When did you lecture, what
13 for?
14 A. Pardon me?
15 Q. What did you lecture on?
16 A. You know, it's hard for me
17 to remember. I believe it was just a
18 general seminar about epidemiology.
19 Q. So it wasn't a class?
20 A. No.
21 Q. What year do you think that
22 was?
23 A. Oh, I can't recall.
24 Q. But you do recall being an

<p style="text-align: right;">Page 22</p> <p>1 assistant professor from 2000 to 2006 at 2 Vanderbilt? 3 A. That was my appointment, 4 yeah. 5 Q. Do you recall the first time 6 that you ever had your deposition taken? 7 A. I don't recall. It's been a 8 long time ago. 9 Q. You don't remember your 10 first? 11 A. No, it's probably been more 12 than 20 years ago. 13 Q. You don't think -- does 2005 14 sound right? 15 A. I don't know. I can't 16 recall. I'm sorry. It's not something 17 that I do regularly. So it's not 18 something that I keep in mind. 19 Q. Were you an expert in the 20 welding rod litigation? 21 A. I did two studies on welding 22 rods, yeah. 23 Q. Say that again. 24 A. I did two studies on welding</p>	<p style="text-align: right;">Page 24</p> <p>1 your deposition taken before?" And your 2 answer was, "Never"? 3 A. Right. 4 Q. Does that refresh your 5 recollection as to when your first 6 deposition was? 7 A. No. I mean, this is 8 15 years ago. It's hard to remember that 9 far back. 10 Q. So you think that you might 11 have had a deposition before this? 12 A. I don't think I did. I'm 13 not sure. 14 Q. Okay. You don't recall this 15 deposition back in 2005, but you remember 16 being an associate professor at 17 Vanderbilt from 2000 to 2006? 18 MR. BALL: Objection to 19 form. 20 THE WITNESS: Being an 21 associate professor is much more 22 meaningful to my career, of 23 course. 24 BY MR. VAUGHN:</p>
<p style="text-align: right;">Page 23</p> <p>1 rods. And yes, I did. 2 Q. You did studies. Were you 3 an expert in that litigation? 4 A. I'm not sure how they 5 classified me. 6 Q. Did you testify? 7 A. I gave a deposition. I 8 didn't testify in court. 9 Q. Why's that? 10 A. Pardon me? 11 Q. Why's that? Why didn't you 12 testify in court? 13 A. I have no idea. 14 MR. VAUGHN: Tyler, can we 15 open up 2005 Fryzek welding rod 16 depo. 17 (Document marked for 18 identification as Exhibit 19 Fryzek-5.) 20 MR. VAUGHN: Can we go to 21 Page 9. 22 BY MR. VAUGHN: 23 Q. Line 17. Doctor, do you see 24 where you are asked, "Have you ever had</p>	<p style="text-align: right;">Page 25</p> <p>1 Q. Why is an associate 2 professor meaningful to your career? 3 A. Pardon me? 4 Q. Why is it meaningful to your 5 career? 6 A. Because it's an academic 7 appointment. 8 Q. Were you paid? 9 A. You know, I'm not -- I can't 10 recall if I was paid or not. It was part 11 of my affiliation with the International 12 Epidemiology Institute. 13 MR. VAUGHN: Okay. Tyler, 14 can we go to Page 103 now of that 15 deposition. 16 BY MR. VAUGHN: 17 Q. So line 10, they ask what 18 your current responsibilities at 19 Vanderbilt are. And you answer, "Working 20 on grants," correct? 21 A. Oh, yeah. Yep. 22 MR. VAUGHN: And then, 23 Tyler, can we go to the next page. 24 BY MR. VAUGHN:</p>

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1 Q. And then when they ask you
2 how long you have been affiliated with
3 Vanderbilt there on Line 18 and 19, you
4 answered two years.
5 And this was in 2005,
6 correct?
7 A. I said I think it's been two
8 years.
9 Q. And so you think you were
10 wrong at that time?
11 A. You're asking about stuff
12 that happened more than 15 years ago. I
13 can't recall.
14 Q. Okay.
15 MR. VAUGHN: Tyler, can we
16 go to Page 113 now.
17 BY MR. VAUGHN:
18 Q. Line 10, have you ever
19 applied to be a professor or instructor
20 at Vanderbilt or any other teaching
21 institution. You answered, "I -- I was
22 an assistant professor at University
23 Nebraska Medical Center."
24 And then Line 17 through 19,

Page 27

1 "Since then, have you applied for a
2 position or instructor or teacher or
3 professor at any other institution?"
4 What was your answer at that
5 time?
6 A. I said no.
7 Q. No. So in 2005, you did not
8 think that you were an assistant
9 professor at Vanderbilt University,
10 correct?
11 MR. BALL: Objection to
12 form.
13 THE WITNESS: I'm sorry, can
14 you repeat that question? I
15 didn't quite understand it.
16 BY MR. VAUGHN:
17 Q. In 2005 you did not think
18 you were an assistant professor at
19 Vanderbilt, correct?
20 MR. BALL: Same objection.
21 THE WITNESS: I'm not clear
22 how you're getting that
23 conclusion.
24 BY MR. VAUGHN:

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1 Q. All right. Well, you see
2 the question on Line 17 through 19?
3 A. Yeah. Right.
4 Q. Okay. So it's asking after
5 1996, have you ever applied for a
6 position or instructor or teacher or
7 professor at any other institution, and
8 you said no.
9 Correct?
10 A. Mm-hmm.
11 Q. So how were you an assistant
12 professor at Vanderbilt at that time if
13 you had not applied to be a professor at
14 any institution since 1996?
15 MR. BALL: Objection to
16 form.
17 THE WITNESS: It's through
18 my work at International
19 Epidemiology Institute.
20 So eventually Vanderbilt
21 absorbed International
22 Epidemiology Institute. So it was
23 part of that. I didn't apply for
24 it.

Page 29

1 BY MR. VAUGHN:
2 Q. Well, why when you were
3 asked the questions Lines 10 through 12
4 when I asked if -- sorry, on line --
5 yeah, 10 through 12, when they asked if
6 you'd been a professor at Vanderbilt, why
7 was your answer that you were an
8 assistant professor at Nebraska, why
9 didn't you just say yeah?
10 MR. BALL: Objection to
11 form. Argumentative.
12 THE WITNESS: I wasn't a
13 professor or instructor at
14 Vanderbilt. I was an assistant
15 professor.
16 BY MR. VAUGHN:
17 Q. Which is what you answered
18 for University of Nebraska. You said, "I
19 was an assistant professor for University
20 of Nebraska."
21 Why didn't you just say I
22 was an assistant -- I am an assistant
23 professor for Vanderbilt?
24 MR. BALL: Objection.

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1 Argumentative.
2 THE WITNESS: Yeah, sorry,
3 you're asking me about what I said
4 15 years -- more than 15 years
5 ago. I can't recall.
6 BY MR. VAUGHN:
7 Q. Would you not defer to what
8 you gave under oath 15 years ago about
9 events that happened 15 years ago?
10 MR. BALL: Objection.
11 Argumentative.
12 THE WITNESS: Well, this
13 is -- yeah, this is going back to
14 1996. That's what, 30 years ago.
15 BY MR. VAUGHN:
16 Q. Yeah, I'm talking about this
17 part of your CV that says you're an
18 assistant professor at Vanderbilt from
19 2000 to 2006, which you deferred to your
20 recollection in 2005.
21 A. I would trust my CV.
22 Q. Who put your CV together?
23 A. Right now it's -- my
24 administrator does.

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1 Q. Is it -- who is the
2 administrator?
3 A. Shelley Fierstein.
4 MR. VAUGHN: All right. Can
5 we go back to his CV, Appendix A.
6 On Page 3 of the doc. Yeah.
7 THE WITNESS: I don't think
8 you have my most current CV that I
9 sent.
10 BY MR. VAUGHN:
11 Q. That's unfortunate. That's
12 what you guys sent us.
13 MR. BALL: That's incorrect.
14 My colleague just told me that you
15 have the most recent updated one.
16 When did you send it,
17 Coleen?
18 MS. HILL: With his
19 production materials.
20 MR. BALL: With his
21 production materials.
22 MR. VAUGHN: So Appendix A
23 to his expert report is not his
24 most up-to-date?

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1 MR. BALL: That's correct.
2 It doesn't look like it from what
3 I'm seeing.
4 BY MR. VAUGHN:
5 Q. What's missing?
6 A. I'd have to go through it
7 and see it, compare it to my current one.
8 Q. Is there anything inaccurate
9 in this one?
10 A. We'd have to go through it
11 and see.
12 Q. Has there ever been stuff
13 that's inaccurate in your CV?
14 MR. BALL: Objection to
15 form.
16 THE WITNESS: I can't
17 recall.
18 THE VIDEOGRAPHER: Off the
19 record, 9:16.
20 (Brief pause.)
21 THE VIDEOGRAPHER: We are
22 back on the record at 9:21 a.m.
23 MR. VAUGHN: Can we stay
24 with that last exhibit we were on

Page 33

1 before we switched it?
2 TRIAL TECH: Appendix A?
3 MR. VAUGHN: Correct.
4 BY MR. VAUGHN:
5 Q. At the bottom, Doctor, you
6 see this is a July 2021 version of your
7 CV, correct?
8 A. Mm-hmm. Yeah. Correct.
9 Q. All right. And if we go
10 back up under academic appointments, do
11 you see it lists Georgetown, 2020 to
12 present?
13 A. Right.
14 Q. And then this visiting
15 professor at Denmark, you note is from
16 2011 to present, and at University of
17 Pittsburgh, 2011 to present.
18 A. Yes.
19 Q. This was produced with your
20 expert report, correct?
21 A. I'm not sure. I sent you
22 the most current one where those are
23 updated.
24 Q. Okay. These ones were

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1 updated July of 2021, right?
2 A. I believe so. I guess.
3 MR. VAUGHN: Okay. Tyler,
4 now can we go to the CV that I
5 dropped into the chat as the next
6 exhibit. And then next page.
7 BY MR. VAUGHN:
8 Q. And so at the bottom here,
9 we can see that this one was updated in
10 September of 2021 now, right?
11 A. Right.
12 Q. And this is the new version
13 that you're talking about?
14 A. Yes, sir.
15 Q. And then if we can go back
16 to academic appointments, so the
17 University of Pitts -- in Pennsylvania,
18 University of Pittsburgh went from 2011
19 to present, to 2011 to 2020.
20 A. Yes.
21 Q. So is that an error on your
22 previous CV?
23 A. It was.
24 Q. And then for Denmark, it

Page 35

1 went from 2011 to present and now it's
2 all the way back to 2016. Was that also
3 an error in your CV?
4 A. Yes.
5 Q. But the University of
6 Vanderbilt still says 2000 to 2006,
7 doesn't it?
8 A. Yes.
9 Q. Are you going to change that
10 on your future CVs?
11 A. Change what?
12 MR. BALL: Objection to
13 form.
14 BY MR. VAUGHN:
15 Q. Your 2000 to 2006 assistant
16 professor, that in 2005 you said you were
17 not?
18 A. Oh, no. This is -- this is
19 correct.
20 Q. How did you get the
21 appointment at Denmark?
22 A. I've done research
23 collaboration with them since about 1996,
24 '97.

Page 36

1 Q. Who is "them"?
2 A. Danish researchers.
3 Q. I'm sorry?
4 A. I still do collaboration
5 with them.
6 Q. Are they at certain
7 institutes or anything?
8 A. Yeah. It's -- it's here,
9 the Department of Clinical Epidemiology,
10 Aarhus University.
11 Q. Is there any other
12 organizations in Denmark that you do
13 research with?
14 A. Sometimes I do stuff with
15 the Danish Cancer Society in Copenhagen.
16 Q. How long have you been
17 working with them?
18 A. Since '97, '98. You can see
19 on my CV when I started publishing with
20 them.
21 Q. Have any of your companies
22 ever funded any of the Danish
23 organizations?
24 A. Oh, I have no idea.

Page 37

1 Q. Do you -- if they collate
2 data for you from the cancer database, do
3 you pay them for that?
4 A. So now, the way that I cover
5 it with them now is they're a
6 subcontractor.
7 Q. What does that mean?
8 A. They get paid as a
9 subcontractor.
10 Q. You said the way that you
11 handle it now. How did you previously
12 handle it?
13 A. Oh, I wasn't in charge of it
14 before -- back in the early 2000s when I
15 was -- I mean, I -- so I don't know how
16 they did it.
17 Q. And EpidStat, has it always
18 been a subcontracting position?
19 A. Yes.
20 Q. And so EpidStat gets paid,
21 and they pay them out of that money?
22 A. Yes.
23 MR. BALL: Objection to
24 form.

Page 38

1 Hey, Jon, you've got to give
2 me a chance to object, please.
3 THE WITNESS: Okay. I've
4 got to put the screen back so I
5 can see him.
6 BY MR. VAUGHN:
7 Q. So when you were visiting
8 professor in Denmark, how often did you
9 visit this university?
10 A. Oh, I was going there every
11 six months before Covid, even -- even
12 until today.
13 Q. What were you doing when you
14 were visiting that university?
15 A. Collaborating on research.
16 Q. Did you ever teach?
17 A. I don't believe so. I don't
18 think I even gave a lecture. No, I gave
19 a lecture once.
20 Q. Of all your academic
21 appointments, which ones did you actually
22 teach?
23 A. Georgetown.
24 Q. And that's where you are

Page 39

1 currently at?
2 A. Yep. Oh, also at Michigan I
3 did, so...
4 Q. What did you teach at
5 Georgetown?
6 A. Epidemiology.
7 Q. What is an adjunct
8 professor, what's different than that
9 than a regular professor?
10 A. Adjunct professor, you just
11 get paid. So you don't get on the tenure
12 track or anything like that, any of the
13 benefits, stuff like that.
14 Q. How many hours a week do you
15 spend teaching?
16 A. So it's the spring class at
17 Georgetown, and I teach on Thursday
18 nights. The class, I think, is three
19 hours.
20 Q. Is that in person or via
21 Zoom or some other platform?
22 A. Oh, it's through Zoom, of
23 course, through Covid.
24 Q. Why in your CV does it not

Page 40

1 list an employment history?
2 A. That's just standard for
3 EpidStrategies, ToxStrategies. I did
4 give my employment history in my report.
5 Q. So is that policy at
6 EpidStrategies, that you don't give
7 employment history?
8 A. ToxStrategies, yeah. You
9 can look at everyone's -- everyone's CV.
10 It's the same.
11 MR. VAUGHN: Can we go back
12 to his expert report again, Tyler.
13 Let's go to Page 2.
14 THE WITNESS: I'm going to
15 look at my report here as well, if
16 that's okay?
17 BY MR. VAUGHN:
18 Q. Yeah, if you ever need more
19 time when we're going through stuff to
20 review something to answer a question,
21 just let me know, okay?
22 A. Thank you. Yeah.
23 Q. All right. So it's fourth
24 paragraph down. You note that you worked

Page 41

1 in the pharmaceutical industry from 2006
2 to 2012.
3 And then are these positions
4 after -- where -- are they where you were
5 working in the pharmaceutical industry
6 from those years?
7 A. Yes.
8 Q. And so you worked at Amgen?
9 A. Amgen. Yes.
10 Q. Amgen?
11 A. Yeah.
12 Q. And is that a subsidiary of
13 another company?
14 A. No. It's a huge company
15 that's about 25,000 employees.
16 Q. And then you worked at
17 MedImmune?
18 A. Yes.
19 Q. Do you know what --
20 A. MedImmune doesn't exist
21 anymore. It's -- AstraZeneca's absorbed
22 it.
23 Q. Okay. And so what years
24 approximately were you working at Amgen?

Page 42

1 A. Amgen.
2 Q. Amgen. I'm sorry.
3 A. That's all right. I think
4 it's about 2006 to 2009, I think. Yeah,
5 it's 2009, 2010, so...
6 Q. And then MedImmune would
7 have been -- was that after or at the
8 same time?
9 A. Yeah. No, that was
10 afterwards. Amgen is in Los Angeles and
11 MedImmune is out here in Maryland. So...
12 Q. And so when you said that
13 your employment history was in your
14 expert report, is this what you're
15 talking about?
16 A. Yes, sir.
17 Q. Did you not work anywhere
18 before 2006?
19 A. I think it says up above.
20 Let's see. Yeah. The
21 paragraph right before that, it says, "I
22 joined the faculty of the University of
23 Nebraska Medical Center."
24 Q. And you didn't have any

Page 43

1 other jobs around this time?
2 A. I'd just graduated from
3 University of Michigan, so that was my
4 first job after graduating.
5 Q. Did you work for any other
6 research companies around 2000?
7 A. Let's see, 2000 -- no.
8 Q. Early 2000s?
9 A. No. It was International
10 Epidemiology Institute.
11 Q. And did they pay you?
12 A. Oh, yes.
13 Q. But you don't consider that
14 as part of your employment history?
15 A. It is, absolutely.
16 Q. And is that listed here?
17 A. International Epidemiology
18 Institute, yes. It's the -- it's the
19 last sentence of that paragraph.
20 Q. Oh, I see it. I see it.
21 Thank you.
22 A. Yep.
23 Q. And then from 2006 to 2012,
24 were you working at any other place

Page 44

1 during this time?
2 A. You mean besides the ones
3 that I've listed here?
4 Q. Yeah.
5 A. No.
6 Q. Have you ever worked for a
7 company called Exponent?
8 A. Oh, I did for one year, yes.
9 Q. What year was that?
10 A. It wasn't even a year.
11 It was -- I can't recall.
12 It was before I formed EpidStat.
13 Q. 2010, 2011 sound about
14 right?
15 A. Maybe. I'm not sure. I
16 can't recall.
17 Q. Did you leave Exponent to
18 open EpidStat?
19 A. Yes.
20 Q. Why?
21 A. Because I wanted to do
22 pharmacoepidemiology, and so more of an
23 opportunity to do it on my own.
24 Q. Does Exponent do that type

Page 45

1 of work too?
2 A. Well, they tried with me.
3 But it didn't really work.
4 Q. Why didn't it work?
5 A. There wasn't a lot of
6 support for it.
7 Q. How so?
8 A. In terms of personnel,
9 knowledge, things like that. I published
10 a few things in the pharmacopeia world
11 while I was at Exponent, but not much.
12 Q. Did you open EpidStat
13 yourself?
14 A. No.
15 Q. Who opened it with you?
16 A. David Garabrant.
17 Q. Does he have any
18 relationship with Exponent?
19 A. Not to my knowledge.
20 Q. How do you know David
21 Garabrant?
22 A. He was my mentor at
23 University of Michigan.
24 Q. When did EpidStat get

Page 46

1 acquired by ToxStrat?
2 A. EpidStat, you mean?
3 Q. Yeah?
4 A. EpidStat no longer exists.
5 It wasn't acquired.
6 Q. EpidStrategies, is that what
7 it's called?
8 A. Yeah.
9 Q. Does that still exist?
10 A. EpidStrategies does. That's
11 who I work for now. Yes. It's a
12 subsidiary of ToxStrategies.
13 Q. And so it's not the same as
14 EpidStat was?
15 A. EpidStat.
16 Q. Stat?
17 A. We all are -- yeah. No, we
18 all -- most of the folks from EpidStat
19 moved over to EpidStrategies. So it's
20 almost the same people.
21 Q. Do you know the people that
22 opened ToxStrategies?
23 A. Pardon me?
24 Q. The people that opened

Page 47

1 ToxStrategies, do you know them?
2 A. Yes.
3 Q. Who are they?
4 A. It's three of them; Laurie
5 Haws, Deb Proctor, and Mark Harris.
6 Q. How many of them are
7 previous employees of Exponent?
8 A. Oh, I don't -- I don't know
9 their employment history.
10 Q. You don't know if they each
11 left Exponent to open this?
12 A. I don't -- yeah, I don't
13 know.
14 Q. Do you know if ToxStrategies
15 is owned by another company?
16 A. No, it's not.
17 Q. It's its own company?
18 A. Yeah.
19 Q. So EpidStat is where you
20 were previously, and now it's called
21 EpidStrategies?
22 MR. BALL: Objection to
23 form.
24 BY MR. VAUGHN:

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1 Q. Was it just coincidental
2 that you guys named your companies so
3 similar, yours being EpidStat and theirs
4 being ToxStrategies or ToxStat -- Strat?
5 A. ToxStrategies. They just
6 wanted to be EpidStrategies so it kind of
7 flowed, you know, so...
8 Q. When you were running
9 EpidStat, would it be fair to
10 characterize that institute as a research
11 institute that provides expert assistance
12 on the evaluation of complex health
13 issues, and on the conduct and
14 interpretation of epidemiological studies
15 to pharmaceutical and medical device
16 companies?
17 MR. BALL: Objection to
18 form.
19 THE WITNESS: I'm not sure
20 what you're reading. But I don't
21 know.
22 MR. VAUGHN: Okay. Tyler,
23 can we go to 2018 indirect
24 treatment comparison.

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1 (Document marked for
2 identification as Exhibit
3 Fryzek-7.)
4 BY MR. VAUGHN:
5 Q. Second page. On that
6 left-hand side under Competing Interests,
7 it says --
8 A. Can you blow that up a
9 little bit? I'm sorry.
10 Q. Yeah, the JPF, is that -- is
11 that your initials?
12 A. Yes, sir.
13 Q. All right. "Are employees
14 of EpidStat Institute." Can you read
15 that sentence for me?
16 A. JPF, HR, LT, and DDA are
17 employees of EpidStat Institute, which is
18 a research institute that provides expert
19 assistance on the evaluation of complex
20 health issues and on the conduct and
21 interpretation of epidemiological studies
22 to pharmaceutical and medical device
23 companies."
24 Q. Is that accurate?

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1 A. That is accurate, yep.
 2 MR. VAUGHN: And can we go
 3 back to his invoices, Tyler. Jon
 4 Fryzek invoices IMS.
 5 BY MR. VAUGHN:
 6 Q. All right. And so we see
 7 your name on these first ones, and I
 8 think if we add those up it comes out to
 9 14.5 hours on this bill.
 10 Does that look correct to
 11 you?
 12 A. I don't know. You want me
 13 to add them up?
 14 Q. Sure.
 15 A. 14.75.
 16 Q. 14.75, cool.
 17 And then who is Mina Suh.
 18 Did I say that right?
 19 A. Yep.
 20 Q. Who is she?
 21 A. She is an epidemiologist.
 22 Q. Does she work for you?
 23 A. Yes. It's Mina Suh.
 24 Q. Mina Suh. Are you aware

Page 51

1 that she previously worked at Exponent?
 2 A. I have no idea. She was at
 3 ToxStrategies when I joined.
 4 Q. Ok. Is that the first time
 5 you met her?
 6 A. Yes.
 7 Q. And so does she work for
 8 ToxStrategies or the EpidStrategies?
 9 A. She was working for
 10 ToxStrategies and she moved over to
 11 EpidStrategies when we came.
 12 Q. So you guys kind of work
 13 with whoever on that? I mean you can
 14 pull from ToxStrategies or EpidStrategies
 15 for your work, does it work that way?
 16 MR. BALL: Objection --
 17 sorry. Objection to form.
 18 THE WITNESS: Sometimes. It
 19 depends on the project.
 20 MR. VAUGHN: Okay. Can we
 21 go to the next page, Tyler.
 22 BY MR. VAUGHN:
 23 Q. So we've got 6.5 hours
 24 billed on this one from you, correct?

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1 A. It looks like, yep.
 2 Q. And who is this Janice
 3 Lansita?
 4 A. She used to be an employee
 5 at ToxStrategies, but she -- she left
 6 because of Covid.
 7 Q. So she doesn't work there --
 8 doesn't do work for you anymore?
 9 A. No. She just -- she doesn't
 10 do any work, so...
 11 Q. Did she leave like in the
 12 middle of 2020?
 13 A. I don't recall when she
 14 left.
 15 Q. Was it recent or has it been
 16 about a year ago?
 17 A. Yeah, it's been a while.
 18 When things shut down with Covid she left
 19 to take care of her kids.
 20 Q. Okay. And so this Mina
 21 Suh -- how do you say it again, Mina?
 22 A. Suh.
 23 Q. Suh. So she's doing
 24 42 hours here. She's doing quite a bit

Page 53

1 of the work on the research of this
 2 expert report, right?
 3 A. No.
 4 MR. BALL: Objection to
 5 form.
 6 BY MR. VAUGHN:
 7 Q. What do you mean no?
 8 A. This is back in 2019. So
 9 this is -- at the beginning she did.
 10 Q. Okay. Yeah. Okay.
 11 MR. VAUGHN: Let's go to the
 12 next page.
 13 BY MR. VAUGHN:
 14 Q. This is still early, this is
 15 2019. So you billed one hour on this
 16 one, right?
 17 A. Yes.
 18 Q. And the rest was Mina Suh?
 19 A. Pardon me?
 20 Q. And the rest of them was
 21 Mina -- oh, I guess Sarah Cohen billed
 22 per hour, and then the rest of the
 23 billing was Mina Suh again?
 24 A. Yeah. Yes. I'm sorry.

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1 Q. Next page. Not much on that
2 one. Let's go to the next page. Just
3 the Sarah Cohen. Next page.
4 Professional support staff. What is
5 that? Previously you'd been identifying
6 people.
7 A. Yeah, I don't know. It's
8 a -- must be an admin thing.
9 Q. Would that be someone within
10 the company, professional support staff,
11 or has that been outsourced?
12 A. No, it's within company.
13 What year is this? This was
14 2020? Yeah.
15 Q. So we're now at the end of
16 2020. You just have a few hours billed
17 still.
18 Let's go to the next page, I
19 think we start doing your billing now.
20 All right. So now we are in 2021. And I
21 showed this being about 14.75 hours from
22 you, and then 43 hours from professional
23 support staff that's not identified,
24 correct?

Page 55

1 A. How did you get 14.75?
2 Q. I added up 1, 1.5, 1, .75,
3 1, 1, 1, .5, 3, 1, 1, 2.
4 A. You're right.
5 Q. Okay. The next page. So
6 here we have another three hours here
7 from you. What I found really
8 interesting is that we're in 2021 now,
9 and Janice Lansita is billing hours
10 again?
11 A. No, that's -- that must be
12 an error or something. I have no idea.
13 She's retired.
14 Q. So are you guys going to
15 refund that money or how does that work?
16 A. This is the first I've
17 seen --
18 MR. BALL: Objection to
19 form.
20 THE WITNESS: Sorry, I have
21 no idea.
22 BY MR. VAUGHN:
23 Q. Are you going to notify your
24 clients about that billing error?

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1 A. You already have, so... my
2 client is sitting here, so...
3 Q. Are you going to notify
4 those within your company of this billing
5 error?
6 A. I have no idea what happens
7 to that, so...
8 Q. Who enters the billings?
9 A. The administrators. One of
10 the advantages of not having my own
11 company is I don't have to pay to the
12 invoicing -- pay attention to the
13 invoicing like I used to when I had my
14 own company.
15 Q. And who at your company now
16 is it, again, that pays attention to the
17 invoicing? What's their name?
18 A. Mark Harris does all that.
19 He's one of the cofounders.
20 Q. And you're not aware if he
21 previously worked at Exponent, are you?
22 A. No idea.
23 MR. VAUGHN: Let's go to the
24 next page.

Page 57

1 BY MR. VAUGHN:
2 Q. All right. I added up that
3 you billed 15.75 hours here. And then in
4 Janice Lansita again, now she's billed
5 46 hours in 2021.
6 A. Yeah.
7 Q. Another billing error?
8 A. I have no idea. As I said,
9 this is the first time I'm looking at
10 these.
11 Q. That obviously isn't right,
12 correct? I mean, she didn't work there
13 then.
14 MR. BALL: Objection to
15 form.
16 THE WITNESS: It must be the
17 incorrect name.
18 BY MR. VAUGHN:
19 Q. What name do you think it
20 should be?
21 A. Oh, I have no idea.
22 Q. Were you working with the
23 staff in doing all this work in preparing
24 your expert report?

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1 A. Absolutely.
2 Q. I mean, this was just six
3 months ago, and it's the person --
4 whoever was spending the most time on
5 this project, you don't know who was
6 spending the most time on this project?
7 MR. BALL: Objection to
8 form.
9 THE WITNESS: Yes, I do.
10 BY MR. VAUGHN:
11 Q. Who is it?
12 A. Sue Pastula.
13 Q. Sue who?
14 A. Pastula.
15 Q. So you think -- you think
16 that's who that was billed to, is her?
17 A. I assume so, yes.
18 Q. How long has she worked
19 there?
20 A. She's worked there, I think,
21 about a year. I'm not sure when she
22 started. She came over from EpidStat
23 too.
24 Q. And how long did she work at

Page 59

1 EpidStat before?
2 A. Well, the whole time that we
3 were there, she worked with David
4 Garabrant since the '90s.
5 Q. Well, shouldn't they know
6 who she is then and not think she's
7 Janice Lansita?
8 MR. BALL: Objection to
9 form.
10 THE WITNESS: I would think
11 so. But as I said, I'm not in
12 charge of the billing. So that's
13 a billing error they'd done.
14 BY MR. VAUGHN:
15 Q. Have you ever had billing
16 errors in previous litigations that
17 you've worked on?
18 A. Not to my knowledge.
19 Q. You don't remember any of
20 that with the welding rod litigation?
21 A. I don't recall.
22 Q. You don't recall. Okay.
23 MR. VAUGHN: Let's go ahead
24 and go to the next page.

Page 60

1 BY MR. VAUGHN:
2 Q. You have 3.5 hours billed on
3 this one.
4 A. Yep.
5 Q. And again, we've got
6 57 hours from Janice Lansita?
7 A. Yeah. It must be Sue
8 Pastula. So they've got the wrong name.
9 Q. I don't know if I see her
10 name disclosed anywhere in this. I'll
11 keep looking.
12 A. Yeah, that's why I'm
13 thinking -- that's why I'm thinking it
14 must be Sue. As I said, I can't -- I
15 don't know unless I look.
16 MR. VAUGHN: Next page.
17 BY MR. VAUGHN:
18 Q. It looks you got 13 hours
19 here. You've got Janice Lansita. The
20 next page is just Sarah Cohen.
21 MR. VAUGHN: And let's go to
22 the next one.
23 BY MR. VAUGHN:
24 Q. And how many people work at

Page 61

1 EpidStrategies right now?
2 A. I believe we're at eight,
3 eight or nine.
4 Q. Can you list all eight or
5 nine employees?
6 A. Yep. It's myself. Sarah
7 Cohen, Mina Suh, Naimisha Movva, Lauren
8 Bylsma. Heidi Reichert, Xiaohui Jiang.
9 I think I've got them all. I think
10 that's all of them.
11 Q. And so on this one, this
12 38 -- 33 hours for professional support
13 staff, that's just going to be several of
14 them working on it, you think?
15 A. Yeah.
16 Q. How do they keep their hours
17 for that? Do they just -- are they each
18 keeping their own time and then adding it
19 together?
20 A. We have billing software.
21 MR. BALL: Object to form.
22 BY MR. VAUGHN:
23 Q. How does that billing
24 software work for professional support

Page 62

1 staff?
2 A. Oh, I have no idea.
3 Q. When you billed your time,
4 you bill it under -- you bill it under
5 your name, right?
6 A. Correct.
7 Q. If someone's billing under
8 their own name, would they not be
9 included under the professional support
10 staff?
11 MR. BALL: Objection to
12 form.
13 THE WITNESS: Yeah. As I
14 said, I don't know. I'm not in
15 charge of the invoicing anymore,
16 so.
17 BY MR. VAUGHN:
18 Q. And let's go to the next
19 page. This is really recent. This is
20 just last month. So this is all of you
21 billing on most of this time, except for
22 a little bit of Janice Lansita. Actually
23 you got 16 hours here.
24 A. Okay.

Page 63

1 Q. All right. If I add all
2 those up, I come out to 113 hours. Does
3 that sound approximately right to you for
4 the amount of time that you've spent on
5 this?
6 A. Absolutely no idea.
7 Q. No idea. So you have no
8 reason to disagree with me?
9 A. I have no reason to agree or
10 disagree with you.
11 Q. If we added up all those
12 hours, you would agree that's how much
13 time you spent on this expert report?
14 A. If all the hours are added
15 up correctly from the invoices, then
16 that's how much time I spent.
17 MR. VAUGHN: Tyler, can we
18 pull up the ToxStrat mobile
19 document.
20 (Document Marked for
21 identification as Exhibit
22 Fryzek-8.)
23 BY MR. VAUGHN:
24 Q. Did EpidStrat, did they

Page 64

1 have -- did you have a website before you
2 were acquired?
3 A. I'm sorry?
4 Q. Before you were -- before
5 you started working at ToxStrategies,
6 your old company, the EpidStat --
7 A. Oh, yes, EpidStat.
8 Q. Did you have a website with
9 them?
10 A. With who? We had our own
11 website.
12 Q. Your own website?
13 A. Yeah.
14 Q. Is that different -- a
15 different website than what's used now?
16 A. Yes.
17 Q. Okay. On this exhibit, is
18 this a correct representation of where
19 all ToxStrategies is located?
20 A. Oh, I have no idea.
21 Q. How many people work at
22 ToxStrategies outside of -- outside of
23 your department?
24 A. Yeah, I believe it's about

Page 65

1 60 total. But I'm not sure of the exact
2 number.
3 Q. Does that 60 count
4 EpidStrategies?
5 A. Yeah. But it's approximate.
6 I don't know the exact number.
7 Q. And how do you know that
8 ToxStrategies is not owned by another
9 company?
10 A. Because they told me.
11 Q. Who is they?
12 A. The three owners.
13 MR. VAUGHN: Tyler, can we
14 open up now the Exponent mobile
15 web page.
16 (Document Marked for
17 identification as Exhibit
18 Fryzek-9.)
19 BY MR. VAUGHN:
20 Q. It looks pretty similar,
21 doesn't it?
22 A. No.
23 Q. No? I mean --
24 MR. VAUGHN: Tyler, can you

Page 66

1 do a aide-by-side?
2 TRIAL TECH: Yeah, just give
3 me one second.
4 MR. VAUGHN: No rush.
5 BY MR. VAUGHN:
6 Q. You guys are both in
7 Seattle, correct?
8 A. It looks like it, yep.
9 Q. And then both in San
10 Francisco Bay area, correct?
11 A. Yeah. It's not the same
12 offices. These were different companies.
13 Q. And then on one of them, it
14 says Orange County, and the other one it
15 says southern California. But then it
16 says Orange County under that, correct?
17 A. What -- what are you
18 reading?
19 Q. Southern California. So on
20 Exponent, it says Southern California,
21 but then under it, it says Orange County.
22 ToxStrategies, it just says Orange
23 County, right?
24 A. Right.

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1 Q. You're both in Austin and
2 Houston, correct?
3 A. It looks like it, yep.
4 Q. And Exponent lists Denver
5 while ToxStrategies lists Boulder which
6 is right outside of Denver, correct?
7 A. I have no idea. I believe
8 they are quite far apart.
9 Q. And then Exponent lists
10 Detroit, and ToxStrategies lists Ann
11 Arbor.
12 A. Yeah. The Ann Arbor office
13 is all my employees.
14 Q. That Dr. Garabrant that you
15 were talking about earlier, where does he
16 live?
17 A. He lives in -- I believe he
18 lives in Ann Arbor, as far as I know.
19 Q. Okay.
20 MR. VAUGHN: You can go
21 ahead and take that down Tyler.
22 Can we go back to his CV?
23 THE WITNESS: Is this the
24 more recent one or old one?

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1 TRIAL TECH: Most
2 up-to-date.
3 MR. VAUGHN: It says
4 August 2021 at the bottom.
5 THE WITNESS: Okay, thank
6 you.
7 (Document marked for
8 identification as Exhibit
9 Fryzek-6.)
10 BY MR. VAUGHN:
11 Q. Let's go to Page, 3 I think.
12 So at the bottom we have book chapters
13 that I'm looking at. You've published
14 quite a few book chapters, haven't you,
15 Doctor?
16 A. I think just two. Not very
17 many.
18 Q. Oh, is the next page not
19 book chapters too? No, it's manuscripts.
20 Okay. So are these all the
21 book chapters you've ever published?
22 A. Yes.
23 Q. And then the next page I
24 guess it says manuscripts. What are

Page 69

1 manuscripts?
2 A. Scientific manuscripts
3 published in journals, scientific
4 journals.
5 Q. So these are published?
6 A. Yes. Except for the first
7 one. The first one says in press so it
8 hasn't been published yet.
9 Q. The studies you publish, are
10 they typically funded?
11 A. Sometimes, sometimes not.
12 Q. Can you give an example of
13 one that was not funded?
14 A. It will take me a bit to go
15 through my CV.
16 Is there -- is there a
17 way --
18 Q. There is. But do you not
19 recall just offhand the last time you've
20 done a nonfunded study?
21 A. No. I mean, I've published
22 over 200 things so it's hard to remember.
23 Q. And most of them were
24 funded?

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1 MR. BALL: Objection to the
2 form.
3 THE WITNESS: I don't know.
4 BY MR. VAUGHN:
5 Q. But you can't recall any of
6 the 200 that were unfunded as you sit
7 here?
8 A. As I --
9 MR. BALL: Object to form.
10 THE WITNESS: I'm sorry, I
11 would have to look. So...
12 BY MR. VAUGHN:
13 Q. Go ahead.
14 A. I can control it?
15 Q. There should be a way you
16 can download it.
17 TRIAL TECH: So you can --
18 you can do it through the link
19 that was sent in the chat. Either
20 that or I could give you remote
21 control of the screen. It might
22 be easier for you to do it through
23 the link that's on the chat.
24 THE WITNESS: For the marked

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1 exhibits?
2 TRIAL TECH: Correct, yeah.
3 The marked exhibits folder.
4 THE WITNESS: So I have that
5 open. I just need to refresh my
6 window to see it.
7 TRIAL TECH: And this should
8 be -- you want to go to Exhibit 6.
9 THE WITNESS: Thank you.
10 TRIAL TECH: You're welcome.
11 THE WITNESS: Hey guys, so I
12 have access now.
13 Can you repeat your question
14 please.
15 BY MR. VAUGHN:
16 Q. Yeah.
17 Do you recall any studies
18 that you have published that were not
19 funded?
20 A. Either through an NIH grant
21 or other type of research grant or?
22 Q. Just not funded at all.
23 A. Not funded at all. I know
24 one off the top of my head is the

Page 72

1 pancreatic cancer and obesity.
2 Q. Mm-hmm.
3 A. Book chapter on RSV wasn't
4 funded.
5 Q. Did -- sorry.
6 A. Neither book chapter was
7 funded.
8 Q. Okay. So what about these
9 publications though that you published?
10 A. Let's see. So the Le study,
11 Le HQ, Tomenson, it's a review and
12 meta-analysis of occupational titanium
13 dioxide.
14 Q. Why did you do that study?
15 A. Why?
16 Q. Yeah.
17 A. It was interesting. So I
18 had done research on titanium dioxide.
19 Q. What piqued your interest on
20 it?
21 A. I had done research on
22 titanium dioxide.
23 Q. Is there any companies that
24 ever funded you that would be interested

Page 73

1 in that research as well?
2 A. I don't recall.
3 Q. What journal did you publish
4 that in?
5 A. It says here, the Journal of
6 Occupational and Environmental Medicine.
7 Q. Do you publish in that
8 journal a lot?
9 A. I have published before in
10 that journal.
11 Q. Do you think it's a
12 reputable journal?
13 A. I believe so, yeah.
14 Q. Do you think it has industry
15 bias?
16 A. Oh, I have no idea. I don't
17 know what you mean by industry bias
18 either.
19 Q. Did anyone else -- who were
20 the other people that you published with?
21 A. Let's see. They're other
22 epidemiologists, other scientists.
23 Q. And do you know if any of
24 them got any funding to do this study?

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1 A. No idea. I don't believe so
2 though.
3 Q. Do you talk about that
4 before you publish a study?
5 A. No.
6 Q. You don't ask your
7 collaborators, hey, are you guys getting
8 funded by somebody to do this so that you
9 can disclose the conflict of interest in
10 the paper, you don't do that?
11 A. That's the first author's
12 responsibility. So I just worry about
13 the science. Make sure the science is
14 accurate.
15 Q. Can't bias influence the
16 accuracy of science?
17 MR. BALL: Objection to
18 form.
19 THE WITNESS: No.
20 BY MR. VAUGHN:
21 Q. Bias can't -- why do we care
22 about bias then?
23 A. I guess I should --
24 MR. BALL: Objection. I'm

Page 75

1 sorry.
2 THE WITNESS: I'm sorry, I'm
3 getting confused about your
4 question. Can you ask again?
5 BY MR. VAUGHN:
6 Q. Can bias not influence the
7 integrity of a scientific paper?
8 A. You'd have to give me an
9 example.
10 Q. We'll get to them.
11 Your pancreatic cancer and
12 obesity study, why did you do that study?
13 A. Because I was interested in
14 it.
15 Q. Why were you interested in
16 that?
17 A. Because at that time there
18 was a lot of research on obesity and
19 cancer outcomes. So it was one of the
20 first papers to show the relationship
21 between obesity and pancreatic cancer.
22 Good study.
23 Q. Is pancreatic cancer also
24 linked to diabetes? Can pancreatic

Page 76

1 cancer cause diabetes?
2 A. I -- can pancreatic cancer
3 cause diabetes? I have no, no idea.
4 Q. You don't know?
5 A. No, I don't know. I haven't
6 studied that.
7 Q. Do you know if diabetes can
8 cause obesity?
9 A. I don't know that.
10 Q. So you don't know if maybe
11 obesity is a symptom of pancreatic cancer
12 as opposed to a cause?
13 A. So it's established by the
14 American Cancer Society that obesity is
15 related to pancreatic cancer and not
16 through diabetes.
17 Q. You said related. But, I
18 mean, if it was a symptom of, it would
19 still be related. You're saying it's
20 actually a risk factor for?
21 A. Right.
22 MR. BALL: Objection to
23 form.
24 THE WITNESS: You can look

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1 on the American Cancer Society
2 website and find it.
3 BY MR. VAUGHN:
4 Q. What year did you do that
5 study?
6 A. I have to look here to find
7 out.
8 Q. Were you working for anybody
9 at that time?
10 A. I was.
11 Q. Who were you working for?
12 A. International Epidemiology
13 Institute.
14 Q. Is that one of the companies
15 you worked for that gets paid by industry
16 to do studies?
17 MR. BALL: Objection to
18 form.
19 THE WITNESS: It's one of
20 the companies, consulting firms
21 that I worked for, yes.
22 Do you still want me to find
23 out what year that was published?
24 BY MR. VAUGHN:

<p style="text-align: right;">Page 78</p> <p>1 Q. No, that's okay. It was 2 mostly -- more where you were working at 3 the time. So why -- is that the IEI? Is 4 that what it's abbreviated as? 5 A. It was, yes. 6 Q. Is that a for-profit 7 company? 8 A. You know, I don't know. It 9 no longer -- it no longer exists. It's 10 by absorbed by Vanderbilt. 11 Q. By who? 12 A. Vanderbilt. 13 Q. Was it often that they would 14 just fund their own studies? 15 MR. BALL: Objection. 16 Foundation. 17 THE WITNESS: I was just a 18 junior researcher there. So I 19 didn't really pay attention to the 20 funding. 21 BY MR. VAUGHN: 22 Q. So how are you sure that 23 that research for pancreatic cancer and 24 obesity wasn't funded?</p>	<p style="text-align: right;">Page 80</p> <p>1 it wasn't affiliate with it? 2 A. Correct, yeah. 3 Q. And you were doing 4 independent research? 5 A. I was doing that research on 6 my kitchen table at night. I wasn't 7 doing it while I was at work. I was 8 interested in it. 9 Q. What piqued your interest 10 though in that? 11 A. I told you. The pancreatic 12 cancer was my dissertation topic, and 13 there's a lot of studies on obesity and 14 various cancers. And I realized I had 15 the data in my dissertation dataset, and 16 so I analyzed it and wrote a paper. 17 Q. Why did you choose 18 pancreatic cancer for your dissertation? 19 A. I have no -- no reasons. 20 Q. What professor oversaw you 21 for that dissertation? 22 A. Well, there were four of 23 them. So David Garabrant was one. David 24 Schottenfeld. It's been 30 years, sir.</p>
<p style="text-align: right;">Page 79</p> <p>1 MR. BALL: Objection to 2 form. 3 THE WITNESS: Well, easy. 4 Because the data came from my 5 dissertation, my doctoral 6 dissertation. 7 BY MR. VAUGHN: 8 Q. But how do you know that IEI 9 or no one else within IEI or publishing 10 with you was getting funded? 11 MR. BALL: Objection to 12 form. 13 THE WITNESS: On pancreatic 14 cancer. 15 BY MR. VAUGHN: 16 Q. Huh? 17 A. On pancreatic cancer? 18 Q. Yeah. 19 A. Because it wasn't affiliated 20 with IEI. 21 Q. Oh, I thought you said it 22 was IEI? 23 A. Oh. No, no. 24 Q. You were working at IEI, but</p>	<p style="text-align: right;">Page 81</p> <p>1 You know, it's kind of hard for me to 2 remember. Brenda Gillespie was another 3 one. 4 Q. David Garabrant, was he the 5 main one? 6 A. No. Sioban Harlow was the 7 main one. 8 Q. One second. 9 MR. VAUGHN: Go to Page 12. 10 Next page. Keep going. 11 BY MR. VAUGHN: 12 Q. Here. The case reports, 13 letters to the editor, what are -- what 14 are these? 15 A. These are letters to the 16 editor. 17 Q. What are letters to the 18 editor? What does that mean? 19 A. If someone had a comment 20 about a study I did. We had the 21 opportunity to respond. So just a few 22 times there were comments. 23 Q. Why do people comment on 24 your studies?</p>

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1 MR. BALL: Objection to
2 form.
3 THE WITNESS: They have
4 questions.
5 BY MR. VAUGHN:
6 Q. They ever have criticisms?
7 A. Well, with over 200 studies
8 I've done, we've got four. So that's not
9 very often.
10 Q. Has a governmental agency
11 ever criticized your work?
12 A. Not that I'm aware of.
13 Q. Or a health agency ever
14 criticize the work you've done?
15 A. Not that I'm aware of.
16 Q. Not that you're aware of.
17 And then abstracts and
18 presentations, what's an abstract?
19 A. It's a meeting abstract
20 presented at a scientific conference.
21 Q. Okay. So all of these are
22 things that you presented at a
23 conference?
24 A. Well, the first author is

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1 usually the one that presents them. But
2 I was involved in them.
3 Q. A lot of presentations.
4 A. I know. It's been busy.
5 Q. Do you get paid for these
6 presentations?
7 A. It's usually part of the,
8 you know, contract to do the study.
9 Q. What all is included in the
10 contract to do the study, besides the
11 study and the presentation?
12 MR. BALL: Objection.
13 THE WITNESS: Well, I mean
14 if the data warrants it, we do a
15 presentation. So the contract is
16 usually just to do the study and
17 write a report. And if it's
18 interesting, we write a paper and
19 an abstract.
20 BY MR. VAUGHN:
21 Q. What about being an expert?
22 Is that part of the same contract?
23 A. Expert in what?
24 Q. Expert in -- defense expert

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1 in a litigation?
2 A. Part of what contract?
3 MR. BALL: Objection to
4 form.
5 BY MR. VAUGHN:
6 Q. Is it part of the same
7 contract when you do defense work and
8 publish studies, or are they two separate
9 contracts?
10 MR. BALL: Objection to
11 form.
12 THE WITNESS: I'm sorry.
13 I'm confused.
14 BY MR. VAUGHN:
15 Q. Okay. So, like, for the
16 welding rod litigation you did you were a
17 defense expert, and you were also
18 publishing studies. Was that the same
19 contract or did you have two contracts --
20 A. Yeah --
21 Q. -- or more contracts?
22 A. As I said, when I was at
23 IEI, I had no idea how the funding
24 happens. I just got paid a regular

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1 salary.
2 Q. How much did you get paid
3 for the welding rod out of a salary then?
4 Do you know?
5 A. I have no idea. I get a
6 monthly salary, so.
7 Q. And it doesn't depend on
8 your work, the quality, whether it's
9 positive, negative? You just get paid a
10 salary?
11 MR. BALL: Objection to
12 form.
13 THE WITNESS: That's
14 correct.
15 (Whereupon, a discussion was
16 held off the stenographic record.)
17 BY MR. VAUGHN:
18 Q. So you've only published two
19 book chapters; is that right? I'm
20 looking at it.
21 A. That was a lot of work.
22 Q. Oh, All right. I'm not
23 trying to say it wasn't.
24 MR. VAUGHN: Can we, Tyler,

<p style="text-align: right;">Page 86</p> <p>1 go to 2012, Toxic Torts. 2 (Document marked for 3 identification as Exhibit 4 Fryzek-10.) 5 TRIAL TECH: This is 2013. 6 MR. VAUGHN: Thank you. I 7 had a typo. Appreciate it. 8 Making it hard for you. 9 BY MR. VAUGHN: 10 Q. I didn't see this listed 11 anywhere in your CV. Do you recall doing 12 a chapter for Toxic Tort and 13 environmental law defense practice 14 seminar course materials? Do you 15 remember that? 16 A. No. I believe it was a 17 presentation that I gave. I don't 18 believe it was a course. 19 Q. You don't think that you 20 wrote a chapter for it? 21 A. I don't think so. 22 MR. VAUGHN: All right. 23 Tyler, can we go to Page 55. 24 BY MR. VAUGHN:</p>	<p style="text-align: right;">Page 88</p> <p>1 you're calling this a presentation. You 2 didn't list this presentation on your CV 3 either, did you? 4 A. No, but I will. I forgot 5 about it. 6 Q. Oh. Good. 7 A. Thank you. 8 Q. You're welcome. 9 Were you paid for this 10 presentation? 11 A. No. 12 Q. Who contacted you to give a 13 presentation on defense practice 14 seminars? 15 A. It was a presentation -- 16 MR. BALL: Objection to 17 form. 18 THE WITNESS: A presentation 19 on biomarkers. It wasn't on 20 defense practice seminars. 21 MR. VAUGHN: Well, Tyler, 22 can we go back to Page 1. 23 BY MR. VAUGHN: 24 Q. All right. But the entire</p>
<p style="text-align: right;">Page 87</p> <p>1 Q. Use of Biomarkers in 2 Observational Research. And that's you, 3 right, Jon P. Fryzek of the EpidStat 4 Institute? 5 A. Yep. 6 Q. Does this refresh your 7 recollection any? 8 A. Yeah, it was a presentation 9 I gave at a conference. 10 MR. VAUGHN: Can we go two 11 pages after this. 12 BY MR. VAUGHN: 13 Q. This is the table of 14 contents to your presentation. 15 A. Okay. 16 Q. Is that what you would 17 define that as? 18 MR. BALL: Objection to 19 form. 20 THE WITNESS: This is a 21 table of contents, and it looks 22 like it's to my presentation. 23 BY MR. VAUGHN: 24 Q. You didn't list this --</p>	<p style="text-align: right;">Page 89</p> <p>1 seminar was for attorneys that defend 2 toxic torts and environmental law cases, 3 correct? 4 A. I don't know -- 5 MR. BALL: Objection to 6 form. 7 THE WITNESS: I don't know 8 who the conference was for, I'm 9 sorry. 10 BY MR. VAUGHN: 11 Q. Do you see where it says, 12 "The Voice of the Defense Bar," next to 13 dri? 14 A. Yes. 15 Q. Do you know what "the 16 defense bar" means? 17 A. No. 18 I'm sorry, this is the first 19 time I'm seeing this, so... 20 Q. Were you aware that you 21 wrote this chapter or wrote this 22 presentation? 23 A. It's a presentation. I 24 assume it's just my slide deck that I</p>

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1 gave.
2 Q. There's more than just
3 slides. We can go through each page with
4 you, but --
5 MR. VAUGHN: I mean Tyler,
6 let's go to Page 59.
7 BY MR. VAUGHN:
8 Q. Is this like what you would
9 use in your presentation?
10 A. I don't recall this.
11 Q. If you want to download it,
12 feel free or we can scroll through it.
13 A. We can just scroll through
14 it, because I don't recall writing this.
15 Q. Let him know when you're
16 ready for the next page. There's just --
17 it's only like six or seven pages. Maybe
18 ten.
19 A. Can we go to the next page.
20 I just want to flip through it.
21 I don't recall this at all.
22 Okay. Next page. Next
23 page.
24 Because these are parts of

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1 my slides.
2 Q. You think someone else wrote
3 this and put your name on it?
4 A. Oh, I have no idea. I could
5 have written it. But I don't recall it.
6 Q. You do a lot of work for the
7 defense bar?
8 MR. BALL: Objection to
9 form.
10 THE WITNESS: I'm not sure
11 what you mean by that.
12 BY MR. VAUGHN:
13 Q. Well, as a part of this, it
14 says, "The Voice of the Defense Bar,"
15 Defense Practice Seminar Materials.
16 Do you do a lot of work for
17 defense attorneys?
18 MR. BALL: Objection to
19 form.
20 THE WITNESS: What I said
21 was I wasn't paid for this.
22 BY MR. VAUGHN:
23 Q. Yeah, I understand if you
24 weren't paid. But, I mean, is work only

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1 paid?
2 MR. BALL: Objection to
3 form.
4 BY MR. VAUGHN:
5 Q. Does it have to be work to
6 be paid?
7 A. I'm sorry?
8 Q. Do you -- do you consider
9 work, does it have to be paid?
10 A. I have no idea. I'm sorry.
11 Q. Well, I mean, if this isn't
12 work because it wasn't paid, what would
13 you call it?
14 A. Giving a seminar. So...
15 Q. Have you given previous
16 seminars for the defense bar?
17 A. No.
18 MR. BALL: Objection to
19 form.
20 THE WITNESS: This is the
21 only one.
22 BY MR. VAUGHN:
23 Q. Will you be adding this to
24 your CV in the future?

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1 A. Yes. And thank you for
2 reminding me of that.
3 MR. VAUGHN: Do you mind if
4 we take a break? I've been
5 drinking coffee and stuff.
6 THE VIDEOGRAPHER: Off the
7 record, 10:11 a.m.
8 (Whereupon a discussion was
9 held off the record.)
10 (Short break.)
11 THE VIDEOGRAPHER: We are
12 back on the record at 10:24 a.m.
13 BY MR. VAUGHN:
14 Q. You said earlier that you
15 asked someone at ToxStrat if they were
16 owned by another company. Who
17 specifically was it that you asked?
18 MR. BALL: Objection to
19 form.
20 THE WITNESS: I guess I -- I
21 asked when we first talking about
22 joining them, I met with the three
23 founders.
24 BY MR. VAUGHN:

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1 Q. I thought you said that they
2 told you that they were not owned by any
3 other company.
4 A. No, I know they are not
5 owned by any other company though.
6 Q. How do you know that?
7 A. Because of our contracts,
8 who signed the contracts, et cetera.
9 Q. Would the contract have to
10 disclose that if there was a
11 nondisclosure agreement?
12 A. Oh, I have no idea. It's
13 not -- it's not owned by another company.
14 I don't know where you are drawing that
15 conclusion.
16 Q. I'm trying to figure out
17 where you're drawing your conclusion that
18 there's no way it's owned by anybody
19 else.
20 A. Because I think they would
21 have told me, so...
22 Q. When you opened EpidStat,
23 you did it with Dr. Garabrant; is that
24 correct?

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1 A. What about David Garabrant?
2 Q. Is that who you opened
3 EpidStat with, is that what you said?
4 A. Yes.
5 Q. And do you know if he opened
6 it himself personally or under a PLLC
7 named David Garabrant PLLC?
8 A. They are separate entities.
9 Q. So was the PLLC though, did
10 that -- is that what opened it?
11 MR. BALL: Objection to
12 form.
13 THE WITNESS: I don't know
14 what you mean by that.
15 BY MR. VAUGHN:
16 Q. Did his PLLC own EpidStat?
17 A. Oh, no.
18 Q. Never?
19 A. Never. No.
20 Q. And so if there was any
21 articles of incorporation or anything
22 like that in a state that lists David
23 Garabrant, PLLC, that's inaccurate,
24 correct?

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1 MR. BALL: Objection to
2 form. Foundation.
3 THE WITNESS: I guess I'm
4 not clear what you're asking.
5 BY MR. VAUGHN:
6 Q. What does David Garabrant
7 PLLC, do, do you know?
8 A. No. And I'm sorry, I can't
9 really talk about EpidStat, because it's
10 closed. It's been closed for over two
11 years.
12 Q. And so you can't talk about
13 it because it's been closed?
14 A. Because I have an NDA.
15 Q. So you wouldn't be able to
16 tell me if EpidStat was previously owned
17 by Exponent?
18 A. Oh, it's not. I know that.
19 Q. Oh, it's not now because
20 it's not open. Was it ever?
21 A. No.
22 Q. Do you know if David
23 Garabrant, PLLC, has any association with
24 Exponent?

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1 A. Not to my knowledge, no.
2 Q. Do you have an NDA with your
3 current job?
4 MR. BALL: Objection to
5 form.
6 BY MR. VAUGHN:
7 Q. Did you answer?
8 A. I said no.
9 Q. You don't have an NDA?
10 MR. VAUGHN: Go ahead and go
11 to his expert report.
12 BY MR. VAUGHN:
13 Q. At the bottom of the first
14 page you have two opinions.
15 A. I'm sorry. Is it one of the
16 exhibits that I can --
17 Q. Yeah. I mean, you have a
18 paper copy. This is your actual report
19 we're looking --
20 A. Okay. Okay. Thank you.
21 I'm going to have to put my glasses on.
22 Q. No problem. Take your time.
23 A. Okay. Thanks. Okay.
24 Q. At the bottom you have two

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1 opinions. And that's the only -- the
 2 next page goes to different topics. Two
 3 opinions. Can you read the first one for
 4 me?
 5 A. It says, "My opinions
 6 include but are not limited to the
 7 following: Opinion 1. The scientific
 8 evidence does not support an increased
 9 risk of cancer from the low levels of
 10 NDMA or NDEA with the use of valsartan
 11 products."
 12 Q. So you don't -- sorry. Just
 13 the first opinion right now.
 14 A. Okay.
 15 Q. So your opinion is there's
 16 no increase at all in the risk of cancer?
 17 A. It's not my opinion. It's
 18 the scientific evidence.
 19 Q. And is that any cancer or a
 20 specific cancer?
 21 A. It says any cancer.
 22 Q. But when you're saying
 23 increased risk, are you looking at it as
 24 all cancers or are you saying also if you

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1 look at individual cancers, none of them
 2 have an increased risk?
 3 A. I'm looking at the summary
 4 of evidence following the PRISMA
 5 guidelines. Used the PRISMA guidelines
 6 to do a systematic review of the
 7 literature. And it didn't show any
 8 increase of all cancer or any cancer, any
 9 individual cancer, related to valsartan
 10 products.
 11 Q. And when you say low levels,
 12 do you mean under 96-nanograms per day?
 13 A. I mean low levels in
 14 comparison to endogenous formation, diet,
 15 things like that. Just didn't contribute
 16 a lot.
 17 Q. Is it your opinion that
 18 humans are exposed to more NDMA through
 19 their diet than they are through
 20 valsartan products?
 21 A. It's my opinion that humans
 22 are more exposed to NDMA through
 23 endogenous formation. I think studies
 24 have shown that. That's 55 to 75 percent

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1 of the formation, so...
 2 Q. In a person not taking
 3 valsartan, you're talking about?
 4 A. Correct. Well, any people.
 5 Q. How much is formed
 6 endogenously in a day?
 7 A. The actual amount, I don't
 8 know. That wasn't important to my
 9 analysis, to epidemiology.
 10 Q. How can you say that more is
 11 formed endogenously than through a
 12 valsartan pill, if you don't know how
 13 much is formed endogenously?
 14 A. Because we reviewed some of
 15 the literature on that. It's in my
 16 report.
 17 Q. But you can't tell me how
 18 much?
 19 MR. BALL: Objection to
 20 form.
 21 THE WITNESS: May I look at
 22 my report and see if it says?
 23 BY MR. VAUGHN:
 24 Q. Of course you can.

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1 A. So on Page 36, Paragraph 89,
 2 talk about endogenous formation.
 3 Q. How many nanograms a day
 4 would a human be forming endogenously of
 5 NDMA?
 6 A. As I said, that wasn't
 7 important to my analysis. My analysis
 8 was a review of all the epidemiology
 9 studies. And they didn't show any risk
 10 for cancer.
 11 Q. And so you did not consider
 12 how much NDMA is formed endogenously when
 13 forming your opinions, correct?
 14 A. It was -- I listed it here.
 15 So of course it was something that I
 16 considered. But the epidemiology
 17 literature review didn't show an increase
 18 in cancer.
 19 Q. I'm asking about the amount
 20 that is formed endogenously in a day.
 21 You do not know how much is formed in a
 22 day, correct?
 23 A. I don't --
 24 MR. BALL: Objection to

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1 form.
2 THE WITNESS: I don't
3 believe anyone does.
4 BY MR. VAUGHN:
5 Q. Well, then, what was the
6 basis for your opinion a second ago
7 saying more is formed endogenously than
8 is in a valsartan pill?
9 A. Because it says the crude
10 estimate of 45 to 75 percent of total
11 exposure to n-nitroso compounds is from
12 endogenous formation. That's what some
13 studies have shown.
14 Q. What year was this study
15 that you're citing to?
16 A. I don't know. As I said,
17 this wasn't important to me --
18 Q. I think -- I think it's
19 listed here --
20 MR. BALL: Object. Hey,
21 hey, he gets to answer. Don't
22 interrupt him.
23 Go ahead, Dr. Fryzek.
24 THE WITNESS: Okay. Thank

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1 you.
2 As I said, this wasn't
3 important to my review of the
4 epidemiology literature. I looked
5 at epidemiology literature for my
6 opinions. And that didn't show a
7 risk of cancer.
8 BY MR. VAUGHN:
9 Q. And my question, again, was
10 what year was the study that you were
11 citing to. Are you able to determine
12 that by looking at your expert report
13 right there?
14 A. I don't recall. There's
15 two -- there's two articles referenced
16 here, one from 2007 and one from '97.
17 Q. And are you aware what year
18 contaminated valsartan came on to the
19 market?
20 A. I believe it was mid 2000s.
21 Q. What do you mean by mid
22 2000s?
23 A. 2015, '16, '17, something
24 like that.

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1 Q. So it would have been after
2 these studies, correct?
3 A. Correct.
4 Q. And so this 45 to 75 percent
5 wouldn't apply to people that were taking
6 valsartan, correct?
7 A. As I said, that wasn't an
8 important consideration of my review.
9 MR. BALL: Objection.
10 Sorry. Objection to form.
11 BY MR. VAUGHN:
12 Q. Are you standing by your
13 opinion that you believe there is more
14 endogenous formation of NDMA than there
15 is in a valsartan pill?
16 A. My -- my opinion was that
17 the valsartan doesn't cause cancer based
18 on the scientific -- based on the
19 scientific evidence.
20 Q. So you're not going to give
21 an opinion that more NDMA is formed
22 endogenously than is contained in a
23 valsartan pill, correct?
24 A. It depends if I find more

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1 information or not.
2 Q. At this time, based on the
3 information that you have, you will not
4 be giving that opinion, correct?
5 A. My opinion will be I don't
6 know.
7 Q. And if you find more
8 information and you're going to give that
9 opinion, you will notify the attorneys to
10 notify us, correct? You'll amend your
11 report?
12 A. I don't know how they do it.
13 An affidavit, I don't know how they do
14 that.
15 MR. VAUGHN: Can we go back
16 to the first page of his report,
17 Tyler.
18 BY MR. VAUGHN:
19 Q. Doctor, what's the highest
20 level of NDMA that you're aware of in a
21 valsartan pill?
22 A. As I said, that wasn't
23 important to my review.
24 Q. So you have no idea?

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1 A. I have no idea.
2 Q. Do you know the ranges?
3 A. So my review found no
4 relationship between valsartan and
5 cancer.
6 Q. Do you know the ranges of
7 NDMA in the valsartan pills?
8 A. As I said, it wasn't
9 important for my review.
10 Q. And so that wasn't something
11 that you considered when looking at the
12 studies on valsartan contaminated with
13 NDMA?
14 A. That wasn't something that
15 the authors of the studies considered.
16 Q. But when you're looking at a
17 study, do you not look for the strengths
18 and weaknesses of that study?
19 A. I do.
20 Q. So did you not look into the
21 levels of valsartan contaminations
22 amongst the different manufacturers to
23 see if there were any weaknesses in the
24 studies that you cite?

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1 A. I don't understand how that
2 would be a weakness in epidemiology.
3 Q. Is the dose of NDMA in
4 valsartan pills consistent amongst all
5 valsartan pills?
6 A. Oh, that, I don't know.
7 MR. BALL: Objection to
8 form.
9 BY MR. VAUGHN:
10 Q. Excuse me?
11 A. That I don't know. I
12 believe some of the studies that looked
13 at valsartan tried to do a dose-response
14 relationship with various cancers and
15 didn't find any dose-response
16 relationship.
17 Q. What is a dose-response
18 relationship?
19 A. Higher -- higher levels of
20 valsartan cause more cancer. They just
21 didn't see it in the studies.
22 Q. They didn't see higher
23 levels of valsartan causing cancer or
24 higher levels of NDMA?

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1 A. Of -- well, the NDMA in the
2 valsartan.
3 Q. Do you know if they knew the
4 levels of NDMA in the various valsartans?
5 MR. BALL: Objection to
6 form.
7 THE WITNESS: That I don't
8 know. I just know it was
9 published in the paper.
10 BY MR. VAUGHN:
11 Q. Can you read your second
12 opinion for us?
13 A. Yep. Opinion 2?
14 Q. Yep.
15 A. "The scientific" -- "the
16 scientific evidence does not support an
17 association between dietary intake of
18 NDMA or NDEA and the risk of cancer."
19 Q. Not even an association?
20 A. It doesn't support an
21 association, no. You have to look at the
22 totality of the evidence, and I've
23 graphed them nicely in my report so you
24 can see it pretty quickly. There is not

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1 an association.
2 I mean this is even done
3 after decades of research on diet and
4 NDMA and NDEA and cancer, and after
5 decades of research, there's no
6 association.
7 Q. Have you ever done any of
8 that research yourself?
9 A. No. I don't know why that's
10 important.
11 Q. Have you or your company
12 ever done research on various foods'
13 ability to increase the risk of cancer?
14 A. I believe they have.
15 Q. Was that funded by the
16 industry?
17 A. What industry?
18 Q. Was it funded by any
19 corporation that would have an interest
20 in that type of research?
21 MR. BALL: Objection to
22 form.
23 THE WITNESS: I don't
24 believe it's funded by anyone

<p style="text-align: right;">Page 110</p> <p>1 right now, the studies that are 2 going on. 3 BY MR. VAUGHN: 4 Q. Is your company currently 5 doing research into nitrosamines causing 6 cancer? 7 A. Not -- not that I'm aware 8 of. I don't think so. 9 Q. What were you just 10 referencing when you said currently going 11 on? 12 A. You asked me about studies 13 of food and cancer. That's what I was 14 referring to. 15 Q. Do foods contain 16 nitrosamines? 17 A. No. You didn't say that. 18 You said the risk of various foods and 19 cancer. 20 Q. Oh, no, I'm sorry, my 21 question was: Do foods contain 22 nitrosamines? 23 A. Do foods contain 24 nitrosamines?</p>	<p style="text-align: right;">Page 112</p> <p>1 there's not an association with the risk 2 of cancer, again is that -- are you 3 saying cancer as a whole or even 4 individual cancers? 5 A. So all of the studies where 6 you look at all the studies combined, 7 they don't show an association with NDMA 8 or NDEA and cancer overall or individual 9 cancers. 10 Q. Not even colorectal or 11 liver? 12 A. No. You have to look at the 13 totality of the evidence. So all the -- 14 you can't just point to one article or -- 15 Q. Can you access one article -- 16 MR. BALL: Wait -- 17 MR. VAUGHN: I thought he 18 was done. I'm sorry. 19 BY MR. VAUGHN: 20 Q. Continue. 21 A. I'm sorry, I lost my train 22 of thought. 23 Q. You said, "No, you have to 24 look at the totality of the evidence so</p>
<p style="text-align: right;">Page 111</p> <p>1 Q. Yeah. 2 A. Yes. Studies have shown 3 that. 4 Q. What type of foods contain 5 the highest levels of nitrosamines? 6 A. Oh, I don't know off the top 7 of my head. 8 Q. What foods is your company 9 currently studying? 10 A. I don't know -- 11 MR. BALL: Objection to 12 form. 13 THE WITNESS: I don't know. 14 That's not an area I do research 15 in. 16 BY MR. VAUGHN: 17 Q. Then why were you hired to 18 do that research in this case? 19 MR. BALL: Objection to 20 form. 21 THE WITNESS: Because I am 22 an epidemiologist. 23 BY MR. VAUGHN: 24 Q. When you say that with diet,</p>	<p style="text-align: right;">Page 113</p> <p>1 you can't just point to one article" -- 2 A. Or abstract. 3 Q. Oh, sorry, I cut you off two 4 words too soon. 5 Is the inverse also true, 6 you can't just point to one or two papers 7 or abstracts and say that it doesn't 8 cause cancer? 9 A. You have to look at all the 10 evidence that's published. That's what 11 we did with our PRISMA guidelines. 12 Q. In your opinion, you've 13 looked at all the research that was 14 published? 15 A. Absolutely. 16 Q. How many studies did you 17 review? 18 A. We started with over 2,000 19 studies. 20 Q. Did you review all 2,000? 21 A. Members of my team did, 22 yeah. Part of the -- part of the 23 methodology to do it is you have to have 24 multiple reviewers. You can't just have</p>

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1 one -- one reviewer. You have to make
2 sure that reviewers agree, the correct
3 data, abstract, whatever.
4 Q. Where are those thousands of
5 studies listed? I haven't seen that
6 anywhere. I see like 90 listed at the
7 end of your report, and that's -- that's
8 all I am aware of.
9 A. You have to look at the
10 PRISMA diagram, which is on page -- let
11 me see -- Page 12. So we started out
12 with 1,884 studies.
13 Q. How many did you guys
14 exclude?
15 A. It says -- it's pretty clear
16 in this diagram.
17 Q. Yeah, I'm asking a question.
18 How many did you exclude?
19 A. It looks like we started out
20 with 1,774 excluded, and then we excluded
21 some more after that.
22 Q. Of the 1,884 studies, how
23 many actually remained?
24 A. That we analyzed, 25.

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1 Q. So you analyzed 25 studies?
2 A. But we went through 1,884
3 studies.
4 Q. Where do I find a list of
5 those studies?
6 A. The 1,884?
7 Q. Yeah.
8 A. You can type in our keywords
9 into these databases and you can
10 replicate the analysis. That's why --
11 that's why we did the PRISMA analysis, so
12 other people can replicate it.
13 Q. Why didn't you list that on
14 your materials considered?
15 MR. BALL: Objection to
16 form.
17 THE WITNESS: List what?
18 BY MR. VAUGHN:
19 Q. The 1,884 pieces of
20 literature that your team reviewed.
21 Why is that not listed on the materials
22 considered?
23 A. Oh, I have no idea. I can
24 send those to you if you want them.

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1 Q. Oh, that would be great if
2 you can get a list together of the ones
3 that you guys actually reviewed.
4 MR. BALL: We'll take it
5 under consideration. As he
6 pointed out, he followed the
7 PRISMA guidelines so they can
8 replicate this. So we'll take it
9 under consideration.
10 BY MR. VAUGHN:
11 Q. Would you guys have
12 studied -- reviewed?
13 A. Sorry --
14 MR. BALL: I'm sorry?
15 BY MR. VAUGHN:
16 Q. Would you guys have
17 downloaded and studied all those studies
18 that you reviewed?
19 A. Yes. To review them, we
20 would download them and saved them.
21 Q. And the billing that we went
22 over earlier for your expert report, all
23 of that time that would be captured for
24 the review of these 1,884 studies?

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1 A. Yes. It's a lot of time as
2 you can see from the billing.
3 I just want to be clear,
4 that this is -- this is very typical of
5 how you do a PRISMA methodology to look
6 at the narrative review.
7 Q. So this is typical of how --
8 sorry, I didn't mean to interrupt you.
9 Continue.
10 A. This is -- this is just
11 following the PRISMA guidelines. This
12 graph even comes from the PRISMA website.
13 Q. So did you employ your
14 typical methodology when doing this
15 expert report?
16 A. Yeah. So we do this for any
17 type of review, even review articles we
18 publish.
19 Q. And is this the same
20 methodology that you've used when you've
21 previously been an expert in a
22 litigation?
23 A. It's the standard
24 methodology to do a literature review.

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1 So of course.
2 THE VIDEOGRAPHER: I hate to
3 interrupt. Doctor, I'm getting a
4 lot of lot of noise on your
5 microphone.
6 (Whereupon a discussion was
7 held off the record.)
8 THE VIDEOGRAPHER: Off the
9 record 10:44.
10 (Brief pause.)
11 THE VIDEOGRAPHER: Back on
12 the record at 10:45 a.m.
13 MR. VAUGHN: Tyler, can we
14 go to Page 3 of his expert report
15 now.
16 BY MR. VAUGHN:
17 Q. We have materials reviewed.
18 How did you come into possession of these
19 documents?
20 A. They were sent to me.
21 Q. Who sent them to you?
22 A. Attorneys. I can't remember
23 which one.
24 Q. Defense attorneys?

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1 A. Yes.
2 Q. Did you request any
3 additional documents after they sent you
4 these?
5 A. No.
6 Q. Is there a reason that it's
7 only Teva and Mylan documents?
8 A. I have no idea.
9 Q. Did you not review any
10 internals from any other company?
11 A. Our focus was really on the
12 scientific literature. It wasn't on
13 these documents.
14 MR. VAUGHN: Tyler, can we
15 go to Page 9 now.
16 BY MR. VAUGHN:
17 Q. So on 23, is that the PRISMA
18 guidelines that you've been talking
19 about?
20 A. Yes.
21 Q. Okay. And then so for this
22 first one under 24, your search terms,
23 can you explain how this works for me?
24 Search term --

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1 A. So the --
2 Q. Yeah, like this little graph
3 thing here, where it's like category,
4 search terms and stuff. What does this
5 mean?
6 A. So these are the terms that
7 we actually searched in the database. So
8 we used three databases to search. We
9 used PubMed, Embase and Web of Science.
10 They all give you slightly different
11 articles. Some also mention or list
12 meeting abstracts.
13 So that's why we searched
14 all three of them. And these were the
15 terms that we searched, the terms on the
16 right are the search terms.
17 Q. Okay. So would there be --
18 sorry, continue.
19 A. Well, we filtered them by --
20 we only looked at studies of humans and
21 studies in the English language.
22 Q. And that were on valsartan;
23 is that right? That was for Objective 1,
24 the risk of cancer with exposure to

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1 valsartan products, correct?
2 A. Correct. So valsartan was
3 either listed in the title or abstract or
4 it was a mesh heading, which is a heading
5 that, you know, characterizes the
6 article. It's something that the author
7 has to include.
8 MR. VAUGHN: Tyler, can you
9 go to Page 13.
10 BY MR. VAUGHN:
11 Q. So Number 32, can you read
12 that for me aloud?
13 A. Yes. "Of the included
14 studies, five articles described the risk
15 of cancer with use of NDMA-containing
16 medications, including three studies of
17 valsartan and two studies of ranitidine."
18 Q. Why did you include two
19 studies of ranitidine in your evaluation
20 on if valsartan causes cancer?
21 A. Yeah, that's a good
22 question. When we looked at
23 NDMA-containing medications, those came
24 up. We included them.

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1 Q. Why didn't you include any
2 other ranitidine studies?
3 A. Because they weren't
4 categorized as NDMA-containing
5 medication.
6 Q. You are not aware of other
7 ranitidine studies about NDMA
8 contamination?
9 A. Just the ones that came up
10 in our literature search.
11 Q. What levels of NDMA are in
12 ranitidine?
13 A. Oh, I have no idea.
14 Q. And how is that applicable
15 to if the NDMA in valsartan causes
16 cancer?
17 A. They were another way to
18 look at the data, to look at NDMA. So we
19 just included them.
20 Q. But you have no idea how
21 much NDMA is in ranitidine?
22 A. No. It wasn't important to
23 the studies so.
24 Q. Even if it's not important

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1 to the studies, is it not important to
2 your analysis on if that's applicable to
3 the amount that is in valsartan?
4 MR. BALL: Objection to
5 form.
6 THE WITNESS: I'm not clear
7 how we would analyze it unless the
8 authors reported it.
9 BY MR. VAUGHN:
10 Q. Well, if you're not clear on
11 how to analyze it, then why did you
12 include it in your expert report?
13 A. I didn't say I wasn't clear
14 how to analyze it. I said I'm not sure
15 how I would use that information if it's
16 not reported.
17 Q. Would that not be valuable
18 information if it was reported?
19 MR. BALL: Object to form.
20 THE WITNESS: I'm sorry. I
21 didn't understand.
22 BY MR. VAUGHN:
23 Q. If the levels of NDMA in
24 ranitidine were reported, would that not

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1 be important information for you to
2 consider?
3 MR. BALL: Objection to
4 form.
5 THE WITNESS: I have no
6 idea. I just reported on what the
7 authors of the studies reported.
8 BY MR. VAUGHN:
9 Q. In your opinion, is there
10 more or less NDMA in ranitidine than
11 valsartan?
12 A. Well, I have no idea, but
13 neither type of study showed any risk of
14 cancer. So that's comforting.
15 Q. How important is dose when
16 evaluating a carcinogen?
17 A. So these weren't considered
18 carcinogens by the FDA. They are
19 considered impurities, because there's no
20 relationship with cancer with any
21 NDMA-containing medication.
22 Q. You're saying NDMA is not a
23 probable human carcinogen?
24 A. Not according to the FDA.

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1 They've called it an impurity.
2 Q. You don't think the FDA
3 thinks that NDMA is a potential
4 carcinogen?
5 A. I'm just telling you what
6 they report. I don't know what they
7 think.
8 Q. And because they called it
9 an impurity one time, you think that
10 means it's not a carcinogen now?
11 MR. BALL: Objection to
12 form.
13 THE WITNESS: Well, their
14 whole chapter on NDMA has been
15 referred to as an impurity.
16 BY MR. VAUGHN:
17 Q. Does the FDA talk about how
18 NDMA can increase the risk of cancer?
19 A. I am not aware of that.
20 Q. You're not aware of that?
21 A. Correct.
22 MR. BALL: Objection to
23 form.
24 BY MR. VAUGHN:

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1 Q. Did you not look into that
 2 when doing your expert report?
 3 A. They didn't show any
 4 human --
 5 Q. If the FDA said that NDMA
 6 would increase the risk of cancer in
 7 humans, would you defer to the FDA?
 8 MR. BALL: Objection to
 9 form.
 10 THE WITNESS: I would look
 11 at the articles that they based
 12 that decision on.
 13 BY MR. VAUGHN:
 14 Q. Do you even know what levels
 15 of NDMA the FDA thinks can cause cancer?
 16 MR. BALL: Objection to
 17 form.
 18 THE WITNESS: So the FDA is
 19 a regulatory authority. It's not
 20 a scientific group.
 21 They're looking at NDMA for
 22 different reasons than I am.
 23 BY MR. VAUGHN:
 24 Q. Do you consider the company

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1 you work for to be a scientific group?
 2 A. Absolutely.
 3 Q. Have you ever reviewed any
 4 other ranitidine NDMA studies besides the
 5 two listed in your expert report?
 6 A. Yes. We also -- our
 7 literature search was completed at the
 8 end of January of this year. You know,
 9 since we didn't -- we updated that
 10 through the end of August to see if any
 11 additional or major studies have been
 12 produced since that time. And the
 13 studies of ranitidine didn't show
 14 anything striking in terms of
 15 relationship with cancer. So we didn't
 16 change our conclusions.
 17 Q. Did any of them show an
 18 association with cancer?
 19 A. Nothing that was important.
 20 I don't recall, you know, what they were.
 21 Q. What do you mean "nothing
 22 that was important"? Do you not think
 23 that an increased risk of cancer is
 24 important?

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1 MR. BALL: Objection to
 2 form.
 3 THE WITNESS: It's not me.
 4 You have to look through --
 5 BY MR. VAUGHN:
 6 Q. You're not the one taking
 7 the contaminated valsartan, are you?
 8 MR. BALL: Objection to
 9 form. Argumentative.
 10 BY MR. VAUGHN:
 11 Q. Are you taking the
 12 contaminated valsartan?
 13 MR. BALL: Objection to
 14 form.
 15 THE WITNESS: So I don't
 16 prefer to talk about my medication
 17 usage, and I think you're out of
 18 line with that type of question.
 19 BY MR. VAUGHN:
 20 Q. I'm sorry, you said -- you
 21 said a second ago, "it's not me," when I
 22 asked you if you thought the increased
 23 risk of cancer was important, you said,
 24 "It's not me." So I assumed you meant

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1 it's not me that is taking the
 2 contaminated valsartan that has
 3 carcinogens in it.
 4 MR. BALL: Objection to
 5 form. Is that even -- is that a
 6 question?
 7 MR. VAUGHN: I'm -- yeah.
 8 BY MR. VAUGHN:
 9 Q. Did I misinterpret what you
 10 were saying earlier?
 11 A. I was talking about the
 12 scientists, the published articles on
 13 ranitidine.
 14 Q. And so why do you say "It
 15 wasn't me"? What's the relevance of it
 16 not being -- did you publish any of these
 17 studies that are in your expert report?
 18 MR. BALL: Objection to
 19 form.
 20 THE WITNESS: I'm sorry, I
 21 got lost about what we are talking
 22 about here.
 23 BY MR. VAUGHN:
 24 Q. I asked initially, "Have you

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1 seen any literature on ranitidine where
2 it is associated with an increased risk
3 of cancer?"
4 A. Okay. So I misunderstood
5 what you said. I thought you said if I
6 had seen any additional literature on
7 ranitidine.
8 Q. I asked that first and you
9 said yes. And then I asked if any of
10 that literature showed an increase risk
11 of cancer.
12 A. And I said no. Nothing that
13 was important that would change my
14 opinion.
15 Q. Okay. And I asked what is
16 important to you.
17 A. I said it was not important
18 to me. It's what's important to the
19 people that wrote the articles, the
20 scientists that wrote the articles. I
21 think that's when you tried to
22 personalize it to what medication I was
23 using.
24 Q. Will you be updating your

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1 expert report to contain the additional
2 ranitidine studies that you reviewed?
3 A. I would probably include
4 them, but it won't change my opinions.
5 Q. What would change your
6 opinion?
7 A. If there were a number of
8 studies that showed high risk associated
9 with ranitidine or valsartan, NDMA
10 containing medications.
11 Q. How many studies would be
12 needed for you to draw that conclusion?
13 A. I have no idea.
14 Q. Would three be enough?
15 A. You have to look at a lot of
16 aspects of the study, not just the
17 relative risk. You have to look at, you
18 know, bias, confounding, those type of
19 factors. How well they were conducted.
20 The study design. All sorts of things.
21 Q. Okay. You have critiques of
22 quite a few of the plaintiffs' experts,
23 don't you?
24 MR. BALL: Objection to

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1 form.
2 THE WITNESS: I've critiqued
3 a few of them. My critiques are
4 accurate.
5 MR. VAUGHN: Can we go to
6 Page 55 of his report, Tyler?
7 BY MR. VAUGHN:
8 Q. Do you recall reading
9 Dr. Panigrahy's expert report?
10 A. I do, yes.
11 Q. Do you know Dr. Panigrahy's
12 background professionally?
13 A. I think he is a physician,
14 isn't he?
15 Q. Do you know if he is a
16 researcher as well?
17 A. Maybe a lab researcher. He
18 is not an epidemiologist.
19 Q. Cancer researcher?
20 A. Laboratory worker. I think.
21 But I'm not sure.
22 Q. But he has an M.D. is what
23 you're saying, right?
24 A. I don't know what his titles

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1 are.
2 Q. Do you have an M.D.?
3 A. I have a Ph.D. and an MPH.
4 Q. In 137 are you critiquing
5 his literature review process?
6 A. Let me read it first.
7 Q. Yeah.
8 A. Yes, he didn't follow PRISMA
9 guidelines which are standard guidelines
10 for literature search.
11 Q. And so is your critique that
12 you don't think you can reproduce, find
13 all the studies that he -- he reviewed?
14 A. Well, that is -- that is one
15 concern. It's not --
16 Q. Did you look at his
17 materials considered in his expert report
18 for all the studies that he listed, the
19 hundreds and hundreds and hundreds?
20 A. But the -- you know --
21 MR. BALL: Objection to
22 form -- sorry, Jon. I didn't mean
23 to -- objection to form.
24 THE WITNESS: I don't know

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1 how he identified those. If he
2 just cherry-picked studies to some
3 really positive ones or if he
4 looked at all studies, I just
5 don't know.
6 BY MR. VAUGHN:
7 Q. Do you know if he considered
8 more than 25 studies like you did?
9 MR. BALL: Objection to
10 form.
11 THE WITNESS: So I don't
12 know what he did. He doesn't
13 describe his -- his literature
14 search process.
15 BY MR. VAUGHN:
16 Q. Does he discuss more than
17 25 studies in his expert report?
18 A. Oh, I have no idea.
19 Studies -- he discussed animal studies
20 and mechanistic studies which are out of
21 scope for an epidemiology review.
22 Q. Do you think it's improper
23 that he relied on animal and mechanistic
24 studies?

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1 A. I said I don't know. That's
2 not my critique. My critique is that he
3 didn't report how he did his literature
4 review.
5 Q. Well, if you go to 138, the
6 first thing you say is he "relies heavily
7 on animal and mechanistic evidence."
8 Are you critiquing him for
9 doing that?
10 A. He said he relies heavily.
11 He doesn't rely on the human studies.
12 At the end of the day to
13 understand if something causes cancer,
14 you have to study it in humans, right?
15 To understand if it causes cancer in
16 humans you have to study it in humans.
17 Q. Is that what you're
18 advocating is we test NDMA in humans?
19 MR. BALL: Objection,
20 vague -- objection to form.
21 Argumentative.
22 THE WITNESS: You're
23 twisting my comments, so...
24 BY MR. VAUGHN:

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1 Q. So midway through that
2 paragraph it says, "While important
3 information regarding mechanisms of
4 actions of substances," what's the
5 mechanism of action of NDMA, do you know?
6 A. Not off the top of my head.
7 Q. Do you know if it's a
8 mutagenic -- a mutagenic substance?
9 A. I have no idea.
10 Q. Do you know if it's
11 genotoxic?
12 A. I don't know.
13 Q. You didn't consider if NDMA
14 is a genotoxin or a mutagen in forming
15 your expert opinions?
16 A. I -- to form my expert
17 opinions, I reviewed the epidemiology
18 literature. Epidemiology literature
19 didn't show a relationship between NDMA
20 and humans.
21 MR. VAUGHN: Can we go to
22 the next page, Tyler.
23 BY MR. VAUGHN:
24 Q. I'm looking at 142.

Page 137

1 It says, "In his discussion
2 of latency, Dr. Panigrahy felt that NDMA
3 acts both as a tumor initiator and tumor
4 promoter to activate dormant cancers."
5 Do you -- do you disagree
6 with him on that?
7 A. I don't agree or disagree.
8 Q. Why did you use the word
9 "felt"?
10 A. He did feel it.
11 Q. It's his -- it's his
12 opinion, right?
13 A. Pardon me.
14 Q. It's his expert opinion.
15 It's not just a feeling, right?
16 A. I have no idea.
17 MR. BALL: Objection to
18 foundation.
19 BY MR. VAUGHN:
20 Q. And so you don't agree or
21 disagree with him?
22 MR. BALL: Objection to
23 form.
24 THE WITNESS: Agree or

Page 138

1 disagree about what?

2 BY MR. VAUGHN:

3 Q. About NDMA acting as a tumor

4 initiator and tumor promoter to activate

5 dormant cancers.

6 A. I think that this is just an

7 idea he has. I don't see any evidence to

8 support that.

9 Q. Did you look for any

10 evidence?

11 A. In the studies I did, that I

12 looked at.

13 Q. If NDMA was a mutagen, would

14 it be able to act as a tumor initiator

15 and tumor promoter to activate dormant

16 cancer cells?

17 A. I have no idea.

18 Q. You've never done research

19 on that before?

20 A. No.

21 Q. You then later in the

22 paragraph note, "If NDMA exposure is a

23 trigger for cancer growth and

24 development, cancer incidence would be

Page 139

1 far higher in the general population and

2 the diet studies would show much stronger

3 effects with the daily exposure humans

4 receive from NDMA."

5 Did I read that correctly?

6 A. Yes, but you put emphasis on

7 different words that aren't emphasized in

8 the statement.

9 Q. So as far as what I put

10 emphasis on, I think maybe it was "far

11 higher." What's the cancer rate in the

12 general population? Do you know a

13 percentage?

14 A. No, I don't.

15 Q. Approximate?

16 A. No.

17 Q. Well, how can you make this

18 statement if you don't even know what the

19 general population cancer rate is?

20 A. Because the statement says

21 if NDMA was a carcinogen, it would be

22 higher than what it is.

23 Q. But you can't tell me what

24 percentage of people get cancer in their

Page 140

1 lifetime?

2 A. I'm not sure how that's

3 important to this table.

4 Q. So if one in three people

5 already get cancer in their lifetime,

6 you're saying that even more than that

7 would have to get cancer for NDMA to be a

8 carcinogen?

9 A. So I think you're twisting

10 my words around. I'm not -- I'm not

11 giving absolutes. I'm just saying that

12 there -- it would be more cancer, we'd

13 see a lot more cancer if NDMA was a

14 carcinogen, in diet and other things.

15 Q. Well, wouldn't the inverse

16 be true, if we didn't have it in our diet

17 and we weren't exposed to it all, we

18 would expect lower cancer rates?

19 A. I have no idea.

20 Q. How much NDMA is a human

21 exposed to daily through their diet?

22 A. I don't know.

23 Q. When you say much stronger,

24 that it would show much stronger effects,

Page 141

1 is that not saying that it's already

2 showing effects, diet, NDMA, and cancer?

3 A. I think you're reading too

4 much into one statement.

5 Q. What did you mean by much

6 stronger?

7 A. Why don't you read the whole

8 paragraph. You can't just pull out a

9 statement and say that that's what the

10 paragraph represents.

11 Q. I mean, explain to me what

12 this means. "It would show much stronger

13 effects." Why did you use that language?

14 A. Because that's what --

15 that's what we felt.

16 Q. But the diet studies already

17 are showing an effect of NDMA on human

18 cancer, correct?

19 A. No.

20 MR. BALL: Objection to

21 form.

22 BY MR. VAUGHN:

23 Q. Can you read the next

24 sentence for me, starting with, "The

Page 142

1 studies"?

2 A. "The studies of

3 NDMA-containing prescriptions that had

4 short follow-up time should have seen

5 increased risk of more cancer than just

6 liver cancer if this were true."

7 Q. Is that saying that the

8 NDMA-containing prescription studies

9 showed an increase in liver cancer?

10 A. It doesn't say statistically

11 significant or meaningful.

12 Q. Okay. Does it have to say

13 that?

14 A. Yes.

15 Q. Why?

16 A. Because the Gomm study

17 doesn't show a consistent increased risk

18 of cancer.

19 Q. With the liver.

20 A. With the liver.

21 (Whereupon a discussion was

22 held off the record.)

23 THE VIDEOGRAPHER: Off the

24 record 11:08.

Page 143

1 (Short break.)

2 THE VIDEOGRAPHER: We are

3 back on the record at 11:19 a.m.

4 BY MR. VAUGHN:

5 Q. Doctor, are you familiar

6 with a Grace Chappell, C-H-A-P-P-E-L-L?

7 A. If she works at

8 ToxStrategies, yeah.

9 Q. Yeah, and what -- go ahead.

10 A. She must be one of the

11 junior researchers there that helped us

12 out.

13 Q. What about a Julia Rager?

14 A. That name I'm not familiar

15 with. Is she at ToxStrategies too?

16 Q. Yes, she was it looks like.

17 I don't know if you worked with her. I'm

18 curious if you were familiar with either

19 of them. Do you have any critiques of

20 Grace Chappell?

21 A. No.

22 MR. BALL: Objection to

23 form.

24 MR. VAUGHN: Tyler, can we

Page 144

1 go to 2017, Epigenetics in

2 Chemical-Induced Genotoxic

3 Carcinogenesis.

4 (Document marked for

5 identification as Exhibit

6 Fryzek-11.)

7 MR. VAUGHN: And if we go to

8 Page 2.

9 THE WITNESS: I'm going to

10 have to put this on my other

11 screen so I can see it.

12 BY MR. VAUGHN:

13 Q. Yep.

14 A. Okay.

15 Q. And you see at the top there

16 it notes that they are both at

17 ToxStrategies?

18 A. Okay.

19 MR. VAUGHN: Can we go to

20 the next page, Tyler. Sorry.

21 BY MR. VAUGHN:

22 Q. That second paragraph, it

23 starts with "genotoxicity." Could you

24 read that first line for me aloud?

Page 145

1 A. Yep. So this is from a

2 toxicology journal, it looks like?

3 Q. Yeah, it looks like

4 ToxStrategies was trying to publish this

5 in Opinion -- Current Opinion in

6 Toxicology is the journal.

7 A. It would be nothing that I

8 would ever read.

9 Q. Okay. Can you read this

10 aloud for us?

11 A. Just the first sentence

12 there or you want the whole paragraph?

13 Q. Yeah, start with the first

14 one.

15 A. "Genotoxicity is another of

16 the proposed ten key characteristics of

17 carcinogens and has long been recognized

18 to play an important role in chemical

19 carcinogenesis."

20 Q. And you're not aware if NDMA

21 is a genotoxin, correct?

22 A. As I said, it wasn't

23 important for my studies or my review.

24 Q. Can you read the next

Page 146

1 sentence for me?

2 A. "Genotoxicity is defined as

3 the potential of a chemical to damage

4 DNA, which can result in heritable

5 mutations through cell divisions."

6 Q. Do you know what heritable

7 mutations are?

8 A. I assume that they're

9 mutations that are inherited.

10 Q. So does that mean if it

11 mutates your DNA, that you can pass that

12 onto your children?

13 A. You're asking me a

14 toxicology question. I can't respond.

15 Q. Can you read the next

16 sentence for me?

17 A. "If not properly repaired,

18 such mutations may ultimately lead to

19 carcinogenesis via activation of

20 oncogenes and/or inactivation of tumor

21 suppressors."

22 Q. And if we skip down one, it

23 says, "Additionally, DNA damage

24 associated with chemical exposures may

Page 147

1 act as initiating event in carcinogenesis

2 or it may occur within the sequelae of

3 molecular initiating events."

4 Does this sound similar to

5 what Dr. Panigrahy was saying?

6 MR. BALL: Objection to

7 form.

8 THE WITNESS: This is

9 toxicology. As I said, I'm not a

10 toxicologist.

11 BY MR. VAUGHN:

12 Q. So you weren't critiquing

13 Dr. Panigrahy's opinions related to

14 activation of tumor suppressors?

15 A. I can't remember what I

16 said. You have to show me what I wrote.

17 MR. VAUGHN: We can move on

18 to Page 8 of this study.

19 BY MR. VAUGHN:

20 Q. I notice in your expert

21 report you are talking about blood

22 cancers, you mentioned formaldehyde as a

23 risk factor and then here your colleagues

24 note, "Formaldehyde represents an example

Page 148

1 of a carcinogen that impacts miRNA

2 expression and causes DNA damage."

3 Do you agree with your

4 colleagues?

5 A. I agree -- I have no

6 opinion.

7 Q. Well, you list formaldehyde

8 in your expert report as a risk factor.

9 You don't have an opinion if it's a risk

10 factor for cancer?

11 A. My opinion is that you have

12 to control for it when you look at the

13 relationship between NDMA and cancer.

14 That's what I was trying to control for.

15 Q. Why would you need a control

16 for it if it's not a risk factor?

17 A. I didn't say it wasn't a

18 risk factor.

19 Q. Do you agree that

20 formaldehyde is a risk factor for cancer?

21 A. All that I said is it's

22 something you have to control for when

23 you look at these relationships. You're

24 misinterpreting what I'm saying.

Page 149

1 Q. Well, I'm asking a different

2 question. Do you agree that formaldehyde

3 is a risk factor for cancer?

4 A. I haven't studied

5 formaldehyde so I don't -- studies have

6 shown that and so that's why we said you

7 have to control for it.

8 Q. You need to control for

9 things that you don't even think are

10 necessarily cancerous?

11 MR. BALL: Objection to

12 form.

13 THE WITNESS: I didn't say

14 that.

15 BY MR. VAUGHN:

16 Q. Do you know how IARC

17 classifies formaldehyde?

18 A. I have no idea.

19 Q. You don't know if

20 formaldehyde is a known carcinogen?

21 A. I don't know how IARC

22 classifies it.

23 Q. Outside of IARC, are you

24 aware that formaldehyde is a known human

Page 150

1 carcinogen?
2 MR. BALL: Objection to
3 form.
4 THE WITNESS: As I said,
5 I've never studied formaldehyde.
6 So I have no common knowledge.
7 BY MR. VAUGHN:
8 Q. So you have no reason to
9 disagree with your colleagues that
10 formaldehyde is a carcinogen?
11 A. No reason to disagree.
12 Q. What is miRNA, do you know?
13 A. I don't know.
14 MR. VAUGHN: Next page,
15 Tyler.
16 BY MR. VAUGHN:
17 Q. Bottom of that first
18 paragraph. It says, "These data clearly
19 demonstrate that formaldehyde can
20 significantly alter the expression of
21 miRNAs, including miRNAs that regulate
22 transcriptional targets involved in DNA
23 damage response signaling."
24 So is this saying that

Page 151

1 formaldehyde can also damage DNA?
2 MR. BALL: Objection to
3 form.
4 THE WITNESS: I'm not a
5 toxicologist so I can't interpret
6 these types of studies. I don't
7 know what data they are referring
8 to. I don't know what miRNA mean.
9 BY MR. VAUGHN:
10 Q. And in your opinion, is NDMA
11 carcinogenic to humans at all?
12 A. None of the studies that I
13 reviewed showed that.
14 Q. So you don't think at any
15 level NDMA would be carcinogenic to a
16 human?
17 A. None of the studies --
18 MR. BALL: Objection to
19 form.
20 THE WITNESS: -- have shown
21 a relationship between NDMA and
22 cancer in humans.
23 BY MR. VAUGHN:
24 Q. Would you consider the fact

Page 152

1 that formaldehyde is a known human
2 carcinogen when coming to your opinions
3 on NDMA not being a human carcinogen?
4 MR. BALL: Objection to
5 form.
6 THE WITNESS: I'm sorry, I
7 didn't understand your question.
8 BY MR. VAUGHN:
9 Q. Did you consider the fact
10 that formaldehyde is a known human
11 carcinogen when coming to your opinions
12 that NDMA is not a human carcinogen?
13 MR. BALL: Objection to
14 form.
15 THE WITNESS: I guess I
16 don't understand what you're
17 saying there. I'm sorry.
18 BY MR. VAUGHN:
19 Q. Do you not understand what
20 the relationship is, is that the problem?
21 A. Your sentence doesn't make
22 sense.
23 MR. BALL: Objection to
24 form.

Page 153

1 BY MR. VAUGHN:
2 Q. Explain to me what part
3 doesn't make sense.
4 A. The sentence. I don't
5 understand what you're saying, so...
6 Q. So you don't think that NDMA
7 is a carcinogen, correct?
8 A. Pardon me?
9 Q. You do not believe that NDMA
10 is a human carcinogen, correct?
11 A. Oh, it's not just me. It's
12 the regulatory authorities. It's the
13 studies that we reviewed. It's all the
14 studies.
15 Q. And in coming to your
16 conclusion that NDMA is not a human
17 carcinogen, did you consider the fact
18 that formaldehyde is a known human
19 carcinogen?
20 MR. BALL: Objection to
21 form.
22 THE WITNESS: As it was --
23 as it was studied in the different
24 studies we looked at.

Page 154

1 BY MR. VAUGHN:
2 Q. Did you do any research into
3 how NDMA is metabolized in the human
4 body?
5 A. No. We reviewed the
6 epidemiology literature.
7 Q. So you didn't consider how
8 NDMA is metabolized in the human body
9 when coming to your opinions?
10 A. So that's not something that
11 you commonly consider in epidemiology.
12 Q. You say not commonly. When
13 do you actually consider it in
14 epidemiology?
15 A. I've never considered it.
16 MR. VAUGHN: Tyler, can we
17 go to 1990, Role of metabolism.
18 (Document marked for
19 identification as Exhibit
20 Fryzek-12.)
21 THE WITNESS: This is a 1990
22 paper.
23 BY MR. VAUGHN:
24 Q. It is a 1990 paper. Is that

Page 155

1 too old for us to be relying on? Doctor?
2 A. Oh. Well, you're having me
3 comment on studies that are outside my
4 field. So I don't know how much I can
5 help you on this.
6 Q. Oh, that's okay. I just
7 want to make sure if you knew some stuff
8 or considered it, is mostly what I'm
9 trying to figure out. I need to
10 understand what you considered in forming
11 your expert opinions.
12 A. It's -- I can -- I listed
13 the articles I considered. They are all
14 epidemiology articles, not toxicology
15 articles.
16 Q. This -- in the title where
17 it says dimethylnitrosamine, what is
18 that?
19 A. You have to tell me.
20 Q. You don't know what that is?
21 A. Do you? I mean this is a
22 toxicology paper. I didn't study
23 toxicology. I didn't even have a course
24 of it in college -- in graduate school.

Page 156

1 Q. I just mean this word
2 though. Dimethylnitrosamine. Do you
3 know what that is?
4 A. I have no idea.
5 Q. And so when you were writing
6 your expert report and reviewing
7 literature, you had no idea what
8 dimethylnitrosamine was, did you?
9 MR. BALL: Objection to
10 form.
11 THE WITNESS: You have to
12 explain to me why that's
13 important.
14 BY MR. VAUGHN:
15 Q. Well, what if
16 dimethylnitrosamine is another word for
17 NDMA, would that be important to you?
18 A. If -- if it means the same
19 as NDMA, of course.
20 Q. But you didn't look into
21 that or know that when you were drafting
22 your opinions?
23 A. So the PubMed database that
24 we used would have categorized NDMA with

Page 157

1 dimethylnitrosamine as well. It would
2 have captured it.
3 Q. How do you know that if you
4 don't even know what dimethylnitrosamine
5 meant?
6 A. Because that -- there's
7 something called the mesh headings, which
8 we used.
9 Q. How do you know that it
10 knows it if you don't know it?
11 MR. BALL: Objection to
12 form.
13 THE WITNESS: It's in the
14 National Library of Medicine.
15 BY MR. VAUGHN:
16 Q. Are you making assumptions?
17 MR. BALL: Object to the
18 form.
19 THE WITNESS: I think it's a
20 pretty good assumption.
21 BY MR. VAUGHN:
22 Q. So the answer to my question
23 is yes, you were assuming that the search
24 database knew that dimethylnitrosamine

Page 158

1 was the same as NDMA?

2 MR. BALL: Objection to

3 form.

4 THE WITNESS: You'd have to

5 point me to an epi article that

6 mentioned dimethylnitrosamine. I

7 haven't seen any.

8 BY MR. VAUGHN:

9 Q. So you didn't review any

10 articles on dimethylnitrosamine that were

11 epi studies?

12 A. I'm asking you to show me

13 one.

14 Q. I'm asking you if you

15 reviewed any.

16 A. I don't recall that there

17 was any that were mentioned. I don't

18 know.

19 MR. VAUGHN: Tyler, go to

20 Page 3 of this study.

21 BY MR. VAUGHN:

22 Q. That first paragraph,

23 next-to-last sentence starting with, "The

24 actual enzyme," can you read that aloud

Page 159

1 for me doctor, that sentence?

2 A. That begins with, "The

3 actual enzyme"?

4 MR. VAUGHN: Yeah, there we

5 go. Thank you, Tyler.

6 THE WITNESS: So I will read

7 this sentence from this toxicology

8 journal that is not epidemiology,

9 outside the scope of my field.

10 "The actual enzyme system

11 responsible for the metabolism of

12 DMN, DMN-demethylase, was

13 subsequently characterized by

14 Bouwers and Emmelot by

15 demonstrating that formaldehyde is

16 the main product of in vitro DMN

17 metabolism. Since then, the

18 metabolism of DMN has been studied

19 extensively and has been topic of

20 hundreds of papers."

21 MR. VAUGHN: Can we go to

22 the next page, Tyler.

23 BY MR. VAUGHN:

24 Q. If we look here, we can see

Page 160

1 how NDMA breaks down. Do you see the

2 different spots where it turns into

3 formaldehyde?

4 A. No.

5 Q. You don't see that?

6 A. You'd have to show that to

7 me.

8 Q. On the top right-hand corner

9 it says formaldehyde, and then in the

10 middle right it says formaldehyde.

11 A. Okay.

12 Q. You weren't aware of this in

13 forming your expert opinions, were you?

14 A. I haven't study organic

15 chemistry since I was a junior in

16 college, sophomore in college.

17 Q. Maybe we can get something

18 recent for you because I know you were

19 criticizing that one from being 1990.

20 MR. VAUGHN: Tyler, can we

21 do the 2002 World Health

22 Organization, n-nitroso.

23 THE WITNESS: I didn't

24 criticize that it was 1990. I

Page 161

1 criticized that it was a

2 toxicology article.

3 (Document marked for

4 identification as Exhibit

5 Fryzek-13.)

6 BY MR. VAUGHN:

7 Q. How about a World Health

8 Organization paper, is that better for

9 you?

10 A. Better in what way?

11 Q. Have you ever reviewed this

12 document before, Doctor?

13 A. I can't recall.

14 MR. VAUGHN: Tyler, can we

15 go to Page 19 of the PDF. So 15,

16 then, of the actual paper.

17 There we go. Can you blow

18 up that chart up high?

19 THE WITNESS: Thank you.

20 BY MR. VAUGHN:

21 Q. And, Doctor, what chemical

22 is at the very top middle?

23 A. It says NDMA.

24 Q. And do you see both

Page 162

1 directions where it eventually breaks
2 down into formaldehyde?
3 A. As I said, I don't
4 understand this because I'm not an
5 organic chemist. This is way outside my
6 field.
7 Q. Okay. So again, you didn't
8 consider the fact that NDMA breaks down
9 into a known carcinogen when forming your
10 opinion that NDMA isn't carcinogenic in
11 humans?
12 MR. BALL: Objection to
13 form.
14 THE WITNESS: So, you know,
15 I don't understand the type of
16 formaldehyde. I don't understand
17 all the intricacies of this.
18 BY MR. VAUGHN:
19 Q. What types of formaldehyde
20 are there?
21 A. The epidemiology studies
22 haven't shown a relationship.
23 Q. You said types of
24 formaldehyde. What types of formaldehyde

Page 163

1 are there?
2 A. I have no idea. I said I
3 don't understand. I don't know this.
4 This is outside of my field of study.
5 MR. VAUGHN: Let's go ahead
6 and go back to his expert report,
7 Tyler. Can we go to Page 50 this
8 time.
9 BY MR. VAUGHN:
10 Q. Do you recall reviewing
11 Dr. Etminan's expert report?
12 A. Yes.
13 Q. And do you recall what his
14 profession is?
15 A. I believe he is an
16 epidemiologist. Claims to be an
17 epidemiologist. I don't know.
18 Q. Do you question him being an
19 epidemiologist?
20 A. I question some of the
21 conclusions in this. They're a little
22 goofy.
23 Q. They're a little what?
24 A. Goofy.

Page 164

1 Q. Goofy?
2 A. Absolutely.
3 Q. What's goofy?
4 A. The way he did his
5 literature review, how he interpreted
6 confidence intervals, his review of the
7 occupational study, the Hidajat study. I
8 don't know. It's goofy.
9 Q. So on 128 with the dietary
10 studies. What's your main critique of
11 him using dietary studies?
12 A. I don't have a critique of
13 him using dietary studies.
14 MR. BALL: Jon, you need to
15 speak up just a little. I'm
16 having a hard time hearing you.
17 THE WITNESS: I said I'm not
18 clear what you're asking.
19 BY MR. VAUGHN:
20 Q. Okay. Well, you note in
21 here the exposure estimates are
22 unreliable.
23 A. Yes. That's true for
24 dietary studies.

Page 165

1 Q. Does that make them
2 unreliable, the studies?
3 A. If the exposure estimates
4 unreliable, yes.
5 Q. And so those studies should
6 not be relied on then if they cannot
7 determine accurate exposure estimates?
8 A. So you can't just take, you
9 know, one small phrase from something I
10 wrote and apply it to everything. You
11 have to read the whole thing. Read the
12 whole paragraph, the whole sentence.
13 Q. Why are exposure estimates
14 important?
15 A. Why are they important?
16 Q. Yeah.
17 A. For who?
18 Q. For the validity of a study.
19 A. Because it measures what
20 they are exposed to. I'm not clear what
21 you're asking.
22 Q. What's the problem if you
23 don't have accurate exposure estimates?
24 A. You're not measuring what

Page 166

1 you say you're measuring.
2 Q. Will that impact the results
3 of the study?
4 A. Absolutely.
5 Q. Do you use questionnaires
6 when you do your studies?
7 A. I did them with my
8 dissertation.
9 Q. Is that the only time?
10 A. I'm trying to recall.
11 I believe there were a
12 couple other studies that I did
13 questionnaires as well. But they weren't
14 questionnaires that I developed. I just
15 analyzed them. My dissertation is the
16 only one where I developed the
17 questionnaire.
18 MR. VAUGHN: Tyler, can we
19 now go to the 2005, a cohort study
20 of Parkinson's disease.
21 (Document marked for
22 identification as Exhibit
23 Fryzek-14.)
24 BY MR. VAUGHN:

Page 167

1 Q. Did you do this study while
2 you were working at the IEI that we
3 talked about before?
4 A. Yes.
5 Q. And the Danish Cancer
6 Society, were they involved with this as
7 well?
8 A. It was performed at the
9 Danish Cancer Society.
10 Q. So this is one of those
11 studies that you were talking about that
12 you've worked with the Danish Cancer
13 Society on before?
14 A. Yes.
15 Q. Was this another one you
16 decided to publish in the Journal of
17 Environmental Med -- sorry, Journal of
18 Occupational Environmental Med?
19 A. I'm not sure where it was
20 published.
21 Q. At the bottom of that
22 objective paragraph, is that where -- you
23 published that or is that a citation?
24 A. I'm sorry, where are you

Page 168

1 looking -- oh, it does say Journal of
2 Occupational and Environmental Medicine.
3 Yes.
4 Q. So that's the study that was
5 published in that?
6 A. Yes.
7 Q. Okay. And at this time
8 Sarah Cohen, Loren Lipworth, and William
9 Blot, they all worked with you at the
10 IEI?
11 A. I'm sorry, I can't see
12 because this is blown up.
13 Q. If we go --
14 MR. VAUGHN: Yeah, the
15 bottom part, from the IEI. If you
16 can blow that up.
17 THE WITNESS: Yeah, so
18 it's -- yeah, so you mentioned --
19 yeah, myself, Sarah Cohen, Loren
20 Lipworth, Bill Blott. Yep.
21 BY MR. VAUGHN:
22 Q. Do you currently work with
23 any of these people?
24 A. I work with Sarah Cohen and

Page 169

1 Loren Lipworth once in a while.
2 Q. Where do they work?
3 A. Sarah Cohen works for me.
4 Loren Lipworth is on faculty at Notre
5 Dame.
6 Q. And then who gave funding
7 for this research?
8 A. Oh, I have no idea.
9 Q. Do you see, just a little
10 bit below, it says, "A grant funding this
11 research was provided by a group of
12 current and former manufacturers of
13 welding consumables"?
14 A. Yes.
15 Q. -- see that?
16 A. I wasn't involved in the
17 funding.
18 Q. You weren't involved in the
19 funding?
20 A. No, I was just involved in
21 doing the research at this point of my
22 life.
23 Q. If we go to Page 2. I'm
24 looking at the middle column, basically

Page 170

1 in the middle.
 2 MR. VAUGHN: Yeah, that
 3 paragraph.
 4 BY MR. VAUGHN:
 5 Q. All right. Midway through
 6 it notes that 1986 there was a
 7 self-administered questionnaire that was
 8 mailed to the living workers and their
 9 next of kin or long-term colleagues. Is
 10 that how you guys conducted this study?
 11 A. Oh. So we didn't conduct
 12 the original study. It was an original
 13 study of cancer, I believe. I can't -- I
 14 think it was cancer.
 15 Q. So these questionnaires
 16 weren't even necessarily filled out by
 17 the person being studied, some of them
 18 were filled out by colleagues?
 19 MR. BALL: Objection to
 20 form.
 21 THE WITNESS: I just have to
 22 go with what -- what it says here.
 23 I assume so since I'd be a boy.
 24 BY MR. VAUGHN:

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1 Q. But this was accurate enough
 2 for you guys to use in your study, right?
 3 A. Absolutely.
 4 MR. BALL: Objection to
 5 form.
 6 MR. VAUGHN: If we go to
 7 Page 6, Tyler. And middle again.
 8 And middle of that even.
 9 BY MR. VAUGHN:
 10 Q. It notes job exposures after
 11 this time period were not collected, so
 12 after 1986. And that specific cumulative
 13 exposures information could not be
 14 established.
 15 Did I read that correctly?
 16 A. Yes.
 17 Q. So even though you guys
 18 weren't able to get any information after
 19 1986 and you couldn't figure out
 20 cumulative exposures, it was still okay
 21 for this study, right?
 22 A. Yes.
 23 MR. BALL: Objection to
 24 form.

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1 THE WITNESS: I think the
 2 nice thing about this study is a
 3 couple years ago they did a
 4 follow-up study, found the same
 5 results. To my knowledge.
 6 So if you just Google Johnni
 7 Hansen and Danish welders, you'll
 8 see that they did a follow-up
 9 study.
 10 BY MR. VAUGHN:
 11 Q. Who funded that study, do
 12 you know?
 13 A. I think it says no funding.
 14 But you can look and find out.
 15 Q. Do you always disclose your
 16 funding?
 17 A. I believe we do. I hope we
 18 do.
 19 MR. VAUGHN: Tyler, can we
 20 go to the 2009 welding fume MDL
 21 document.
 22 (Document marked for
 23 identification as Exhibit
 24 Fryzek-15.)

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1 MR. VAUGHN: And then can we
 2 go to Page 45.
 3 BY MR. VAUGHN:
 4 Q. You ever seen this before,
 5 Doctor?
 6 A. No.
 7 MR. VAUGHN: Can you zoom in
 8 on that first paragraph, Tyler?
 9 Yeah.
 10 BY MR. VAUGHN:
 11 Q. Can you go ahead and just
 12 read this entire paragraph aloud for us?
 13 A. I'm sorry, so who is the
 14 author of this paragraph?
 15 Q. Oh, this is by
 16 Judge O'Malley in the Eastern District of
 17 Ohio.
 18 A. Did she write it, or was it
 19 plaintiffs' attorneys or defense
 20 attorneys?
 21 Q. This is the judge.
 22 A. That is the judge.
 23 MR. VAUGHN: Can we go to
 24 Page 73 real quick, just so we can

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1 see the signature.
2 BY MR. VAUGHN:
3 Q. There we go. Kathleen
4 O'Malley.
5 A. Okay.
6 Q. All right. Let's go back to
7 Page 45.
8 All right. Can you now read
9 this paragraph aloud for the jury?
10 A. "Since the beginning of this
11 MDL, the Court has repeatedly addressed a
12 number of issues related to two
13 epidemiological studies known as the
14 Danish and Swedish Studies. Defendants
15 provided funding for both studies, and
16 both studies concluded there was no link
17 between welding and parkinsonism.
18 Recitation of the full and complicated
19 background of the issues related to the
20 Danish and Swedish Studies is beyond the
21 scope of this Order; it suffices to say
22 there were discovery issues related to
23 the two Studies serious enough to give
24 the Court reason to exclude any reference

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1 to them at any MDL trial. Rather than
2 exclude them (as it could have), however,
3 the Court concluded the Studies would be
4 admissible and reference to them by
5 defendants allowed, but that plaintiffs
6 would have 'free rein on cross
7 examination,' including leeway to ask
8 about a long series of issues that went
9 to the credibility of those studies."
10 Q. And that's good. And
11 earlier you testified that you ended up
12 not actually testifying at trial in this
13 litigation, right?
14 A. Right.
15 Q. Do you know if this has
16 anything to do with that?
17 A. I have no idea. What they
18 are talking about here is they wanted
19 access to the data. Well, the data is,
20 you know, the Danish citizens' data and
21 no one could get access to that. They --
22 they --
23 Q. Well, you don't know -- you
24 don't know if they eventually -- oh, keep

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1 going.
2 A. They ended up sending a
3 statistician over there to review the
4 findings.
5 Q. So they did end up reviewing
6 the data, didn't they?
7 A. They sent a plaintiff
8 statistician over there, yes. But they
9 couldn't -- they couldn't release the
10 data outside of Denmark.
11 Q. And if we look at
12 Citation 71, so the first studies that
13 they are talking about is a cohort of
14 Parkinson's disease published by you.
15 That's the study we just looked at,
16 right?
17 A. Right.
18 Q. Okay. And then the second
19 one was by someone named Fored,
20 F-O-R-E-D. How do you say that?
21 A. Oh, Michael Fored.
22 Q. Do you know him?
23 A. Yes.
24 Q. Did you publish with him on

Page 177

1 this other study?
2 A. Yes.
3 Q. You were involved with both
4 studies the judge was talking about?
5 A. Yep. Yes.
6 Q. Were any of the other
7 authors involved with both of the
8 studies?
9 A. I don't know. We have to
10 look at the author list and see.
11 MR. VAUGHN: Okay. Tyler
12 can you pull up 2006 Parkinson's
13 disease.
14 (Document marked for
15 identification as Exhibit
16 Fryzek-16.)
17 MR. VAUGHN: And can you
18 split screen that with the one
19 that we looked at a little bit
20 ago, 2005, A Cohort Study of
21 Parkinson's Disease.
22 BY MR. VAUGHN:
23 Q. Doctor, besides yourself, is
24 there any other author that's on both of

Page 178

1 these studies?

2 A. Bill Blot is. I don't see

3 any others.

4 Q. And Dr. Blot was also

5 working with you at the IEI at that time,

6 correct?

7 A. He was one of the owners of

8 IEI.

9 MR. VAUGHN: All right.

10 Let's only look at the new one,

11 Tyler, the 2006.

12 Can we go to Page 5.

13 Can you blow up the bottom

14 right-hand corner, author

15 affiliations.

16 BY MR. VAUGHN:

17 Q. So it discloses here that

18 you guys were funded by manufacturers of

19 welding consumables again. And it says,

20 "Competing interest, none."

21 Who makes that

22 determination?

23 A. Oh, I have no idea. I

24 assume it's the first author.

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1 Q. Do you agree with that, that

2 you guys don't have any competing

3 interest when you're being funded by the

4 industry that is being sued?

5 MR. BALL: Objection to

6 form.

7 THE WITNESS: I didn't know

8 about any of that when I did the

9 studies. I was just more

10 interested in the science.

11 BY MR. VAUGHN:

12 Q. You didn't know about any of

13 what?

14 A. The litigation going up.

15 Q. You hadn't been hired at

16 this time?

17 What year is this study?

18 A. 2006. Whatever it says.

19 Q. Yeah. Do you recall earlier

20 in your deposition where we reviewed your

21 welding fume deposition? Do you remember

22 what year that was in?

23 A. So mind you, this was

24 published in 2000 -- I don't remember

Page 180

1 when the study was performed.

2 Q. How long does it typically

3 take you to design a study and perform it

4 and write it up?

5 A. At least a year. If not

6 longer.

7 Q. Why is that?

8 A. It's just how long it takes.

9 It takes a long time to write and analyze

10 and submit to a journal, for a journal to

11 review it, send you back comments,

12 respond to the comments. It takes a

13 while.

14 Q. So to have an accurate study

15 it takes quite a while, right?

16 MR. BALL: Objection to

17 form.

18 THE WITNESS: They've

19 expedited that nowadays. But back

20 at this time, it did take longer.

21 BY MR. VAUGHN:

22 Q. If someone was doing a study

23 in two months, would you kind of question

24 it?

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1 MR. BALL: Objection to

2 form.

3 THE WITNESS: Question it?

4 BY MR. VAUGHN:

5 Q. The validity of the study,

6 you know, that they designed it, did the

7 study, wrote it, all within a two-month

8 period. Would you question the validity

9 of it at all?

10 MR. BALL: Objection to

11 form.

12 THE WITNESS: It depends on

13 the study.

14 BY MR. VAUGHN:

15 Q. What's that?

16 A. It depends on the study.

17 Q. What's the fastest you're

18 aware of a study being done?

19 A. I'm sorry. I don't keep

20 track of those types of things.

21 MR. VAUGHN: Tyler, can we

22 go to 2008 New Jersey Law Journal.

23 (Document marked for

24 identification as Exhibit

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1 Fryzek-17.)
2 MR. VAUGHN: And if we go to
3 the next page, left-hand column,
4 starting with "recently." That
5 paragraph and the following
6 paragraph.
7 BY MR. VAUGHN:
8 Q. All right. Doctor, can you
9 read this aloud for us?
10 A. "Recently in December 2007,
11 District Judge Catherine" -- "Kathleen
12 O'Malley who has been handling hundreds
13 of these cases ordered both sides to
14 fully disclose payments made by any of
15 the parties to researchers. Court
16 documents obtained by the Center of
17 Public Health demonstrate that welding
18 organizations pay more than 12.5 million
19 to 25 organizations and 33 researchers,
20 virtually all of whom have published
21 papers dismissing the connection between
22 welding fumes and workers' ailments."
23 Which is true.
24 "Most of the money,

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1 \$11 million, was spent after the
2 litigation achieved critical mass in
3 2003. Attorneys for the welders,
4 meanwhile, spent about half a million.
5 The documents also reveal
6 that Jon Fryzek" -- and my name is
7 misspelled incorrectly -- "who works for
8 Maryland's International Epidemiology
9 Institute, known for its
10 industry-commissioned studies" --
11 I guess I wasn't aware of
12 that.
13 -- "was paid \$971,000 from
14 welding defendants while Paul Lees-Haley
15 was paid \$860,000. C. Warren Olanow, a
16 Manhattan neurologist who published at
17 least a dozen articles cited by defense
18 experts received almost \$2.9 million.
19 The Parkinson Institute in California
20 \$3.4 million to conduct a four-year
21 study."
22 Q. Do you recall now being paid
23 \$971,000?
24 A. No. This study is

Page 184

1 inaccurate.
2 Q. But it isn't a study. This
3 is a --
4 A. Yeah, this review is
5 inaccurate. It's incorrect.
6 Q. So the court documents that
7 were obtained by the Center of Public
8 Integrity are inaccurate?
9 MR. BALL: Objection to
10 form.
11 THE WITNESS: I think how
12 they report it here in this paper
13 is inaccurate. I wasn't paid
14 \$971,000. I wish I was.
15 BY MR. VAUGHN:
16 Q. Are you questioning the
17 integrity of the Center For Public
18 Integrity?
19 MR. BALL: Objection to
20 form.
21 THE WITNESS: I question
22 what's reported here.
23 BY MR. VAUGHN:
24 Q. You don't agree that you

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1 were paid \$971,000?
2 A. No, I wasn't. My life would
3 have been a lot easier.
4 Q. Was IEI paid almost a
5 million dollars?
6 A. Oh, I have no idea.
7 Q. So you're not really aware
8 of where all the money is going to fund
9 what you're doing, are you?
10 MR. BALL: Objection to
11 form.
12 THE WITNESS: When I was at
13 IEI, I wasn't involved in
14 invoicing and those things.
15 MR. VAUGHN: Can we zoom out
16 and go to the next-to-last
17 paragraph in the middle column,
18 Tyler, starting with "finally."
19 BY MR. VAUGHN:
20 Q. It says, "Finally,
21 Dr. Bigler raised serious concerns about
22 the amount of financial incentive paid by
23 defense insurance carriers and corporate
24 defendants to defense forensic

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1 neuropathologist" -- "psychologists."
 2 Do you receive any money
 3 from defense insurance carriers when you
 4 do work?
 5 A. Oh, I have no idea who the
 6 money came from.
 7 MR. BALL: Objection to
 8 form.
 9 BY MR. VAUGHN:
 10 Q. What about since then? Do
 11 you ever --
 12 MR. BALL: Objection to
 13 form.
 14 BY MR. VAUGHN:
 15 Q. -- receive funding from
 16 insurance companies?
 17 MR. BALL: Objection to
 18 form.
 19 THE WITNESS: Not that I
 20 know of.
 21 BY MR. VAUGHN:
 22 Q. Do you have -- okay.
 23 A. Sorry.
 24 Q. Do you know who the

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1 insurance companies are for any of the
 2 defendants in this litigation?
 3 A. No. Again, I think they are
 4 taking just an early slice of what was
 5 going on in this case. Because at the
 6 end of the day, they accept all these
 7 studies and there actually was a review
 8 article written by welders a few years
 9 ago. And the studies are accurate. They
 10 report the science.
 11 Q. Do the defense attorneys
 12 have you testify at trial in this
 13 litigation with welding fumes? No.
 14 A. I never testified at trial.
 15 Q. You've never testified at
 16 trial?
 17 A. Not for this.
 18 Q. Not for this. Oh. I hope
 19 not.
 20 A. Why do you hope not?
 21 Q. I don't think you'd hold up
 22 too well in front of a jury with all
 23 this.
 24 A. Well --

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1 MR. BALL: Objection.
 2 Argumentative.
 3 Excuse me. Mr. Vaughn, if
 4 you keep this up, we're going to
 5 end the deposition. I'm tired of
 6 you insulting his integrity.
 7 MR. VAUGHN: I've got a lot
 8 left.
 9 MR. BALL: That's fine. If
 10 you keep it up, if you keep on
 11 insulting him and making comments
 12 like that, I'm ending the
 13 deposition.
 14 MR. VAUGHN: He asked --
 15 MR. BALL: You can take it
 16 up with the judge.
 17 MR. VAUGHN: Give me a
 18 second. Let's go back to his
 19 expert report.
 20 Page 53 please maybe.
 21 I've got my documents mixed
 22 up. Good job, Brett.
 23 131. We can blow 131 up.
 24 BY MR. VAUGHN:

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1 Q. It's another one of your
 2 critiques of Dr. Etminan. And so can you
 3 explain this critique for us? I don't
 4 want to misinterpret it.
 5 A. Yeah. So he just looks at
 6 the upper confidence limit of any
 7 estimate and uses that, showing that
 8 there's risk but he ignores the lower
 9 limit which is equally likely, and the
 10 lower limit is less than one restriction
 11 of the protective effect of NDMA. You
 12 can't just look at one side of the
 13 confidence interval. No one does that in
 14 my field. Not in a textbook, no other
 15 epidemiologist would say to do that.
 16 Q. Really?
 17 A. Really. And I hope -- I
 18 hope he's not teaching this in his class.
 19 It's inaccurate.
 20 Q. What is your basis that it
 21 would be an equal chance that it reduces
 22 it just because it -- part of it is under
 23 one?
 24 A. If it falls between those

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1 two limits it is equally likely to be as
2 high as it is low.
3 Q. Equally likely?
4 A. Absolutely. You just have
5 to repeat the study over and over. You
6 can't just play with the upper confidence
7 intervals, what he's doing. You can't do
8 that.
9 Q. And so is it your opinion
10 that nonstatistically significant results
11 are useless?
12 A. They don't show a
13 relationship between an exposure and a
14 disease. It would be due to chance.
15 Q. Equally due to chance or
16 could be due to chance?
17 A. Equally likely due to
18 chance.
19 THE COURT REPORTER: Doctor,
20 if you can remove your hand from
21 your face and speak up, please. I
22 would appreciate it.
23 Thank you.
24 THE WITNESS: Yeah.

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1 MR. VAUGHN: Can we now go
2 to 2003, an introduction to power
3 and sample size.
4 (Document marked for
5 identification as Exhibit
6 Fryzek-18.)
7 BY MR. VAUGHN:
8 Q. This -- this is statistics,
9 is this outside of your wheelhouse too or
10 is this part of what you do?
11 A. I do some statistics, but I
12 can't do emergency medicine which is what
13 this journal is published in.
14 Q. So you do some statistics?
15 A. Absolutely. But I have two
16 statisticians that work for me.
17 MR. VAUGHN: Can we go to
18 Page 3, Tyler.
19 BY MR. VAUGHN:
20 Q. On the right-hand column,
21 third paragraph, it starts with when.
22 Can you read that paragraph out loud for
23 us, Doctor?
24 A. "When they are assessing

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1 results from trials with negative results
2 it is particularly important to question
3 the sample size of the study. It may
4 well be that the study was underpowered
5 and that we have incorrectly accepted the
6 null hypothesis, a Type II error. If the
7 study had more subjects, then the
8 difference may well have been detected.
9 In an ideal world this should never
10 happen because a sample size calculation
11 should appear in the methods section of
12 all papers, reality shows us that this is
13 not the case. As a consumer of research
14 we should be able to estimate the power
15 of the study from the given results."
16 MR. VAUGHN: Can we go back
17 to that expert report real quick,
18 I'm sorry, Page 53.
19 BY MR. VAUGHN:
20 Q. And the bottom of that first
21 one, so it would be 129, but we can't see
22 it. Yeah.
23 Do you see that last couple
24 sentences where you're saying, "Power is

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1 set during the design phase ... and is
2 not dependent on the numbers of outcomes
3 identified"?
4 A. Correct.
5 Q. Do you still agree with
6 that?
7 A. Yes.
8 Q. It's not dependent on the
9 number of outcomes?
10 A. No. Power depends on the
11 sample size.
12 Q. If the sample size is too
13 small, will it not catch some of the
14 increased risk if it's a rare outcome?
15 MR. BALL: Objection to
16 form.
17 THE WITNESS: I have no
18 idea. It depends on the study.
19 Depends what you're studying.
20 Depends on a lot of factors. A
21 strong risk factor.
22 MR. VAUGHN: Tyler, let's go
23 to 2004, Cancer risk among statin
24 users.

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1 (Document marked for
2 identification as Exhibit
3 Fryzek-19.)
4 BY MR. VAUGHN:
5 Q. You are one of the authors
6 of this study, weren't you, Doctor?
7 A. Yes.
8 Q. Now, the bottom right it
9 notes that it was -- the grant sponsor,
10 again this Danish Cancer Society, and
11 then International Epidemiology
12 Institute.
13 A. Okay.
14 Q. Who gave the money to the
15 IEI though, do you know?
16 A. I have no idea. Sometimes
17 IEI funded their own stuff. I don't
18 know.
19 Q. Do you think they funded
20 this one?
21 A. I have no idea.
22 MR. BALL: Objection to
23 form.
24 MR. VAUGHN: Can we go to

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1 Page 3.
2 BY MR. VAUGHN:
3 Q. At the bottom right, you
4 note that "The limited number of cancer
5 cases among users of nonstatin
6 lipid-lowering drugs did not allow a
7 thorough examination of site-specific
8 cancer; however, reduced risk estimates
9 were found for several of the selected
10 sites, including colorectal."
11 Did I read that correctly?
12 A. That's what Søren Friis
13 wrote. He is the first author, yes.
14 Q. Do you disagree with it?
15 A. I have no reason to agree or
16 disagree.
17 Q. And so a study the way it's
18 designed can be able to show
19 statistically significant results for one
20 cancer, but if another one is more rare,
21 it might not pick that up, correct?
22 MR. BALL: Objection to
23 form.
24 THE WITNESS: I'm sorry,

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1 could you please ask that question
2 again?
3 BY MR. VAUGHN:
4 Q. So even if a study is
5 properly powered to detect an increased
6 cancer rate in one type of cancer, it
7 might not be powered enough to detect an
8 increased cancer rate in a rarer type of
9 cancer; is that correct?
10 A. Yes, that's correct. But,
11 you know, again it depends on the
12 estimate, what you estimate. The
13 relationship is between the exposure and
14 the outcome. You have to consider that
15 as well.
16 MR. VAUGHN: Can we go to
17 Page 4, Tyler.
18 BY MR. VAUGHN:
19 Q. On the left side, second
20 paragraph.
21 So this paragraph is talking
22 about confounding factors. Midway
23 through it you note that "We aim to
24 address these potential imbalances and

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1 cancer risk factors by including a
2 control group of users of nonstatin
3 lipid-lowering drugs who were likely to
4 be more similar to statin users than
5 individuals in the general population."
6 Can you explain that to me?
7 A. So again, you're asking me
8 to comment on something that I didn't
9 write. You keep saying that I wrote
10 this. Søren Friis wrote this. I just
11 reviewed it.
12 So that's incorrect.
13 Now, let me read this, and I
14 can then comment on it.
15 Okay.
16 Q. Can you just explain to me
17 what that means, though, how your -- how
18 you and your colleagues were balancing
19 the confounders?
20 A. Yeah. So you assume that
21 people that are taking lipid-lowering
22 drugs are similar. So that's what they
23 did.
24 Q. And so that would be the

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1 same for, like, people taking blood
 2 pressure medications, you would assume
 3 they are similar?
 4 A. Yes.
 5 Q. What about people that work
 6 at the same company? Do you assume
 7 they're similar or no?
 8 MR. BALL: Objection to
 9 form.
 10 THE WITNESS: There are so
 11 many factors that goes into that.
 12 Depends on where they work, what
 13 they did, what time period they
 14 worked in. A lot of different
 15 factors go into that.
 16 BY MR. VAUGHN:
 17 Q. But when it's the same drug,
 18 it's pretty well controlled?
 19 MR. BALL: Objection to
 20 form.
 21 BY MR. VAUGHN:
 22 Q. The same kind of drug, I'm
 23 sorry.
 24 A. What's pretty well

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1 controlled?
 2 Q. If you're giving -- if your
 3 control and test group are using the same
 4 classification of drug, that should help
 5 control it?
 6 MR. BALL: Objection to
 7 form.
 8 THE WITNESS: I'm a little
 9 bit confused by your question.
 10 Could you please restate it?
 11 BY MR. VAUGHN:
 12 Q. By having your test and
 13 control group taking the same
 14 classification of medications, does that
 15 reduce confounding factors?
 16 A. What do you mean by test?
 17 Q. When you do a study, do you
 18 have a control group?
 19 A. Sometimes. The control,
 20 comparison --
 21 Q. What group are you comparing
 22 it to?
 23 A. I'm sorry?
 24 Q. What group do you compare

Page 200

1 the control to?
 2 A. So you compare -- it depends
 3 on what your study design is.
 4 Q. Would you have a test group
 5 and a control group?
 6 A. I have not heard the term
 7 test group.
 8 Q. What term do you use?
 9 A. It depends on what -- how --
 10 the study design.
 11 Q. Give me some examples of
 12 terms that you would use besides test.
 13 A. Again, it depends on the
 14 study design. So what study design? I
 15 never heard the term test.
 16 Q. We'll move onto more fun
 17 stuff here in a second then.
 18 Next paragraph where it
 19 says, "Given the widespread rapidly
 20 increasing use of statins, any
 21 association with an increase or decrease
 22 of cancer risk would have a substantial
 23 public health impact."
 24 Do you agree with that?

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1 A. Again, it's difficult just
 2 to pull one sentence out of any kind of
 3 report and say you agree or disagree with
 4 that.
 5 So where are you reading
 6 that?
 7 MR. VAUGHN: Bottom
 8 right-hand corner, Tyler.
 9 BY MR. VAUGHN:
 10 Q. Do you agree that any
 11 association with an increased or
 12 decreased cancer risk would have a
 13 substantial public health impact?
 14 MR. BALL: Objection to
 15 form.
 16 THE WITNESS: It depends how
 17 many folks are using statins now.
 18 I don't know how many folks are
 19 using statins these days. This
 20 paper is 15 years old, so.
 21 BY MR. VAUGHN:
 22 Q. Do you know how many people
 23 are using valsartan nowadays?
 24 A. No.

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1 Q. Would you agree if there is
2 any association with an increased cancer
3 risk of valsartan, it would have a
4 substantial public health impact?
5 MR. BALL: Objection to
6 form.
7 THE WITNESS: So there's no
8 relationship in humans between
9 valsartan and cancer.
10 BY MR. VAUGHN:
11 Q. I said it --
12 A. So there would be no public
13 health impact because there is no
14 relationship.
15 MR. VAUGHN: Tyler, can we
16 go to 2016, American Stat
17 Association.
18 (Document marked for
19 identification as Exhibit
20 Fryzek-20.)
21 BY MR. VAUGHN:
22 Q. Are you familiar with the
23 American Stat Association, Doctor?
24 A. No. But I'm familiar with

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1 the American Statistical Association.
2 Q. That's what I'm talking
3 about. Are they reliable?
4 A. It's a national
5 organizations for statisticians.
6 Q. Okay. Third paragraph.
7 "The P-value was never intended to be a
8 substitute for scientific reasoning."
9 Can you go ahead and read
10 the next sentence for me? It starts with
11 "well-reasoned."
12 A. "Well-reasoned statistical
13 arguments contain much more than the
14 value of a single number and whether the
15 number exceeds an arbitrary threshold."
16 Q. And so do you think you have
17 to have that 95 percent confidence
18 interval for it to actually mean
19 anything?
20 MR. BALL: Objection to
21 form.
22 THE WITNESS: For what to
23 mean anything?
24 BY MR. VAUGHN:

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1 Q. The results.
2 A. Some statistical tests only
3 report P-values. Not all them report 95
4 percent confidence intervals.
5 Q. Can you explain the
6 difference between P-values and
7 95 percent confidence intervals?
8 A. So P-values just tell you if
9 something is statistically significant or
10 not. You can choose whatever level of
11 statistical significance you want.
12 Typically it's .05.
13 The tests that show a
14 P-value or statistical tests that show a
15 P-value of less than .05 are considered
16 to be statistically significant. Their
17 results are likely not due to chance.
18 Confidence intervals tell
19 you, if they are statistically
20 significant or not, as well as the range
21 of potential values for the estimate.
22 Q. So you're critiquing
23 Dr. Etminan for using nonstatistically
24 significant results, but isn't this

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1 saying that that shouldn't be a
2 substitution for scientific reasoning?
3 MR. BALL: Objection to
4 form.
5 THE WITNESS: I'm sorry. I
6 don't understand your question.
7 BY MR. VAUGHN:
8 Q. Isn't this saying just
9 because you don't hit your P-value of
10 .05, it doesn't mean that you just
11 discount your results, right?
12 MR. BALL: Objection to
13 form.
14 THE WITNESS: That doesn't
15 say that. I don't understand how
16 you're coming to it saying that.
17 This is saying not to use
18 P-values, to use 95 percent
19 confidence intervals.
20 BY MR. VAUGHN:
21 Q. Well, again, a second ago
22 you just were talking about P-values and
23 how that shows if it's statistically
24 significant or not.

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1 A. Okay. I was explaining what
2 the P-value meant. I thought you wanted
3 me to explain this.
4 Q. I did want you to because
5 you had said Dr. Etminan used
6 nonstatistically significant results.
7 And you said that the P-value indicates
8 that they're statistically significant.
9 MR. VAUGHN: Tyler, can we
10 go to the next page.
11 MR. BALL: Objection.
12 Argumentative. Was there a
13 question there?
14 MR. VAUGHN: No, I was
15 asking Tyler to go to the next
16 page.
17 MR. BALL: I would
18 appreciate the non-commentary.
19 BY MR. VAUGHN:
20 Q. Okay. Number 2. Can you
21 read that out loud, Doctor?
22 A. "P-values do not measure the
23 probability that the studied hypothesis
24 is true or the probability that the data

Page 207

1 were produced by random chance alone."
2 Q. Weren't you just telling me
3 that it was an equal chance that it was
4 negative and equal chance that it was
5 positive?
6 MR. BALL: Objection to
7 form.
8 THE WITNESS: What was an
9 equal chance?
10 BY MR. VAUGHN:
11 Q. When part of the result was
12 below one, you said that meant it was an
13 equal chance that it was negative.
14 A. So this is talking about
15 P-values, not confidence intervals. They
16 are different things.
17 Q. Oh, so on your -- when
18 you're critiquing Dr. Etminan, you were
19 only talking about confidence intervals,
20 you were never critiquing him on the
21 P-value stuff, right?
22 A. I'll have to read -- I'd
23 have to read what I wrote. I can't -- I
24 can't recall.

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1 Q. You have that on paper,
2 don't you, go ahead and review it.
3 A. Let me find it here and I'll
4 review it.
5 My review of Dr. Etminan
6 doesn't report that Dr. Etminan commented
7 on any P-values.
8 Q. Do you see on Page 54 where
9 you say that he misrepresented the
10 confidence intervals?
11 A. The concept of confidence
12 intervals.
13 Q. Okay. Do you think he was
14 misrepresenting that?
15 A. That's what the statement
16 says, yes.
17 Q. Have you ever been accused
18 of misrepresenting things in your
19 studies?
20 A. No.
21 MR. VAUGHN: Tyler, can we
22 go to the 2013 childhood cancer
23 incidence.
24 (Document marked for

Page 209

1 identification as Exhibit
2 Fryzek-21.)
3 MR. VAUGHN: I thought this
4 was a really interesting article
5 you worked on. My wife is a
6 pediatrician.
7 BY MR. VAUGHN:
8 Q. Do you recall this study,
9 Doctor?
10 A. Yes.
11 Q. And what's this study about?
12 A. It's an ecological study
13 looking at cancer around hydraulic
14 fracturing sites.
15 Q. And do you recall the
16 results of the study?
17 A. I don't.
18 Q. Do you remember who funded
19 it?
20 A. I don't -- I hope it says on
21 here. Does it say on here? Yeah, it
22 says the America's National Gas Alliance.
23 Q. So do you think your
24 findings are probably favorable to them?

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1 MR. BALL: Objection to
 2 form.
 3 THE WITNESS: Well, my
 4 findings are what they are. I
 5 mean you can take -- and do the
 6 same analysis.
 7 BY MR. VAUGHN:
 8 Q. Can you read where it says
 9 under conclusions there in the top left?
 10 A. I wasn't quite done with my
 11 comment.
 12 Q. Oh, I apologize. Continue.
 13 A. You can do the data and do
 14 the analysis yourself if you don't
 15 believe me.
 16 Q. Do you know if anyone else
 17 has looked at that data and done the
 18 analysis and doesn't believe you?
 19 A. Oh, I don't know about that.
 20 Q. What's -- what was your
 21 conclusion here? And you were the lead
 22 author on this one, right? So this was
 23 actually you that wrote it?
 24 A. Yes. "This study offers

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1 comfort concerning health effects of HF
 2 on childhood cancers."
 3 Q. And what's HF?
 4 A. Hydraulic fracking.
 5 MR. VAUGHN: Can we go to
 6 the bottom left, Tyler, on this
 7 page where it has the disclose --
 8 yeah.
 9 BY MR. VAUGHN:
 10 Q. So it notes Dr. David
 11 Garabrant PLLC, and (Pastula and
 12 Ms. Jiang). Do you know who they are?
 13 A. Yes.
 14 Q. How do you know them?
 15 A. They work for me.
 16 Q. Where, at EpidStrategies?
 17 A. Yes.
 18 Q. Have you worked with them a
 19 lot in the past?
 20 A. Yes.
 21 MR. VAUGHN: Can we go to
 22 the fifth page. And the sentence
 23 right before conclusion. If you
 24 can blow that up -- or the two

Page 212

1 sentences. Sorry. As Schoenbach.
 2 Yeah.
 3 BY MR. VAUGHN:
 4 Q. Can you read, starting with
 5 "as Schoenbach" paragraph allowed for me,
 6 Doctor?
 7 A. Yep. "As Schoenbach has
 8 commented, 'When sample populations are
 9 so small that their strata contain mostly
 10 unstable rates and zeroes, the direct
 11 standardization procedure may not be
 12 appropriate and an alternate procedure
 13 becomes desirable.' Therefore, we
 14 believe that the indirect standardization
 15 is preferable and gives a more accurate
 16 representation of the cancer risks
 17 related to HF activities than directly
 18 standardized rates."
 19 Q. Can you explain to me what
 20 that actually means?
 21 A. It just gives confidence in
 22 what we found in our results, the way we
 23 were doing this is correct.
 24 Q. And what was it that you

Page 213

1 did?
 2 A. We did indirect
 3 standardization.
 4 Q. And what is indirect
 5 standardization?
 6 A. It's the way you analyze
 7 your data. So you can do direct
 8 standardization or indirect
 9 standardization. You compare it to a
 10 national rate or a state rate or
 11 something like that. I have to go back
 12 to the method and see who we compared it
 13 to.
 14 Q. Do you think that was proper
 15 to do in this study?
 16 MR. BALL: Objection to
 17 form.
 18 THE WITNESS: Yes.
 19 MR. VAUGHN: Tyler, can we
 20 do 2013 response of obfuscation
 21 does not provide comfort.
 22 (Document marked for
 23 identification as Exhibit
 24 Fryzek-22.)

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1 BY MR. VAUGHN:
2 Q. If we go to Page 2, we can
3 see the title. There we go. The bottom.
4 This is a response to your article on
5 childhood cancer, correct?
6 A. Yes.
7 MR. VAUGHN: And can we go
8 to the next page, Tyler.
9 BY MR. VAUGHN:
10 Q. Who are these people that
11 were critiquing you?
12 A. I believe they are plaintiff
13 experts.
14 Q. At the Public Health of
15 Pittsburgh?
16 A. Pittsburgh Public Health.
17 Q. That was the state that you
18 were doing your study in, right?
19 A. Yes.
20 Q. Do you think they really
21 just have kids in Pittsburgh?
22 MR. BALL: Objection to
23 form.
24 THE WITNESS: I have no

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1 idea.
2 BY MR. VAUGHN:
3 Q. Can you read the -- right
4 above their names where it starts with
5 nevertheless.
6 Can you read that out loud
7 through the end of the paragraph?
8 A. "Nevertheless, in the case
9 of the Fryzek et al study, what the
10 public will hear about UGD and childhood
11 cancer -- likely for the first time -- is
12 controversy engendered by industry's
13 funding of a study that obfuscates" -- I
14 can't say that word very well -- "the
15 issue and does not legitimately address
16 the public's health concerns about the
17 explosive growth of UGD in their
18 backyards."
19 Q. Dr. Fryzek, have you ever
20 been convicted of a crime?
21 A. No.
22 Q. To your knowledge, are you
23 currently under criminal investigation?
24 A. No.

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1 Q. I hope I don't spoil any
2 surprises.
3 MR. VAUGHN: Tyler, can we
4 go to 2020 PA Attorney General's
5 Report.
6 THE WITNESS: What did you
7 say? What was your comment?
8 MR. BALL: What did you say?
9 Did you say you didn't find that
10 surprising?
11 MR. VAUGHN: No, I said I
12 hope I -- the transcript is full
13 of surprises but that's not what I
14 said either. I said I hope I
15 don't spoil any surprises.
16 MR. BALL: Okay. You know,
17 we're done. We're done. That is
18 the third time -- that is the
19 third time you have insulted his
20 integrity.
21 MR. VAUGHN: Okay. Let's
22 just go to Page 9 real quick.
23 MR. BALL: You don't have a
24 basis for this bullshit. We're

Page 217

1 done.
2 MR. VAUGHN: I have a basis.
3 Let me -- let me give my basis and
4 we can take a lunch break.
5 (Document marked for
6 identification as Exhibit
7 Fryzek-23.)
8 BY MR. VAUGHN:
9 Q. You ever seen this document
10 before, Doctor?
11 A. No.
12 MR. VAUGHN: Hey, Tyler, can
13 we go to Page 9.
14 THE WITNESS: I don't even
15 know -- who wrote this?
16 MR. VAUGHN: I guess let's
17 go to Page 3 first then so we
18 can -- sorry, I think PDF Page 3.
19 Page 1 of the doc -- it will say
20 Page 1 -- yeah.
21 BY MR. VAUGHN:
22 Q. So this is in the Court of
23 Common Pleas, Allegheny County,
24 Pennsylvania.

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1 And this is an order
2 accepting and filing investigating grand
3 jury report Number 1.
4 If we go to the next page.
5 We can see that that was signed by the
6 Honorable Norman Krumenacker, the
7 supervising judge for the 43rd Statewide
8 Investigating Grand Jury.
9 A. Well, I don't know what this
10 is.
11 Q. Okay. So now, if we go back
12 to PDF Page 9. All right. And the top
13 right, kind of the first full paragraph,
14 you can see that this is about fracking
15 in Pennsylvania.
16 Do you see that?
17 A. Okay.
18 Q. Okay. And then if we go to
19 the next paragraph where it starts with
20 "the grand jury."
21 Can you read the first three
22 sentences for me?
23 A. "The grand jury began this
24 investigation based on evidence that

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1 private companies engaged in
2 unconventional oil and gas activities
3 have committed criminal violations of
4 Pennsylvania's environmental laws. We
5 found such violations and are issuing
6 several presentments recommending the
7 filing of criminal charges. And we
8 believe investigation of additional
9 crimes should and will continue beyond
10 the term of this grand jury."
11 MR. VAUGHN: All right.
12 Tyler, can we now go to Page 178
13 of this document. And paragraph
14 starts with DOH.
15 BY MR. VAUGHN:
16 Q. Doctor, do you know what the
17 DOH is?
18 A. I assume it means Department
19 of Health.
20 Q. Okay. And can you read the
21 first three sentences of this paragraph
22 aloud as well?
23 A. I'm not sure what Department
24 of Health it is for, because cities have

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1 departments of health, states do.
2 So, "Department of Health
3 staff also engage in research to advance
4 the understanding of health effects
5 associated with fracking. For example,
6 in 2019, under Dr. Levine's direction,
7 DOH and the State of Colorado published a
8 study titled 'A Systematic Review of the
9 Epidemiological Literature Assessing
10 Health Outcomes in Populations Living
11 Near Oil and Natural Gas Operations:
12 Study Quality and Future
13 Recommendations.'
14 "The piece surveyed the most
15 in depth peer-reviewed literature on
16 health effects associated with fracking
17 to date."
18 Q. All right. So this study
19 that the DOH in the state of Colorado
20 published was called "A Systematic Review
21 of Epidemiological Literature Assessing
22 Health Outcomes In Populations Living
23 Near Oil and Natural Gas Operations"; is
24 that correct?

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1 A. Yeah, I'm not sure where --
2 what journal it's published in.
3 Q. That's fine.
4 MR. VAUGHN: Can we go to
5 Page 112 of this document. PDF
6 112.
7 Sorry. 212.
8 BY MR. VAUGHN:
9 Q. Is this a name of the study
10 that we just saw referenced?
11 A. I have no idea.
12 Q. I'm looking at it right now.
13 "A Systematic Review of Epidemiological
14 Literature Assessing Health Outcomes in
15 Populations Living Near Oil and Natural
16 Gas Operations: Study Quality and Future
17 Recommendation."
18 That what this is, right?
19 Okay. And you were asking
20 what journal it was published in. Are
21 you able to tell from this?
22 A. The International Journal of
23 Environmental Research and Public Health.
24 I believe that was plaintiff attorneys.

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1 Q. You think that the
2 Department of Health and the state of
3 Colorado is doing this for plaintiffs'
4 attorneys?
5 A. They published in a
6 plaintiff journal, absolutely.
7 THE COURT REPORTER: Doctor,
8 I cannot hear you. I'm sorry.
9 THE WITNESS: They published
10 in a plaintiff journal.
11 Absolutely.
12 BY MR. VAUGHN:
13 Q. Are you requesting this
14 grand jury's criminal investigation?
15 A. I'm questioning --
16 MR. BALL: Objection to
17 form.
18 THE WITNESS: This journal
19 has been criticized a lot.
20 MR. VAUGHN: Can we go to
21 PDF Page 218. And that bottom
22 paragraph, about midway through.
23 BY MR. VAUGHN:
24 Q. Do you see where they

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1 specifically call you out? "Fryzek, et
2 al., also incorrectly interpreted their
3 standardized incidence ratio results as
4 has been noted by Saunders."
5 A. Okay. I have no idea what
6 they're talking about.
7 Q. And then closer to the
8 bottom, do you see where it says, "ONG
9 operations began in earnest in the late
10 2000s in Pennsylvania, but Fryzek and
11 others use data only through 2009. This
12 truncated period between community
13 exposure and cancer development is a
14 major limitation."
15 Do you see they're talking
16 about you again there?
17 A. Yes. I used all the data
18 that was available.
19 Q. And you still stand by those
20 studies?
21 A. Based on the data we have,
22 absolutely.
23 Q. And no one has recently come
24 to talk to you about your involvement

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1 with those studies?
2 A. I don't even know who
3 Saunders, et al., is.
4 THE COURT REPORTER: Doctor,
5 can you please raise your voice.
6 THE WITNESS: I said if they
7 believed we did something wrong,
8 we should have been made aware of
9 that. This study is quite a few
10 years old.
11 BY MR. VAUGHN:
12 Q. Yeah but some of the grand
13 jury stuff is within the last few months.
14 MR. BALL: Okay.
15 Mr. Vaughn, again, unless you have
16 a basis for suggesting that
17 Dr. Fryzek or his company is under
18 criminal investigation, you're
19 either going to end this line of
20 questioning or we're going to end
21 the deposition. I'm done.
22 MR. VAUGHN: That's fine.
23 I'm done with this line of
24 questioning. I've gotten my clip

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1 back on.
2 If you want to take a lunch
3 break even, we can.
4 Do you want a lunch break?
5 MR. BALL: Sure.
6 MR. VAUGHN: Great. How
7 long do you want?
8 MR. BALL: Half an hour.
9 THE VIDEOGRAPHER: Off the
10 record at 12:31 p.m.
11 - - -
12 (Whereupon a luncheon recess
13 was taken.)
14 - - -
15 THE VIDEOGRAPHER: We are
16 back on the record at 1:07 p.m.
17 - - -
18 CONTINUED EXAMINATION.
19 - - -
20 BY MR. VAUGHN:
21 Q. Doctor, what type of foods
22 contain the highest levels of
23 nitrosamines?
24 A. What types of food?

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1 Q. Yeah.
2 A. I think I wrote about that
3 in the report. Let me look.
4 Q. I think you did as well. I
5 was trying to run a search on it so if
6 you could help me, I'd appreciate it.
7 A. Yeah. It will take me a
8 minute to find it here.
9 On Page 35, Paragraph 86.
10 Q. So the highest levels are
11 in, what is it, processed meats and fish
12 products?
13 A. Yes.
14 TRIAL TECH: Do you want to
15 pull that up, Brett?
16 MR. VAUGHN: No, I think
17 we're okay for now.
18 BY MR. VAUGHN:
19 Q. What type of processed
20 meats, what does that mean?
21 A. I assume it's like salami,
22 and things like that. Bologna.
23 Q. And --
24 A. Hot dogs.

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1 Q. -- does the way the food is
2 cooked impact it at all, do you know?
3 A. I don't know.
4 Q. You didn't consider that in
5 forming your opinions?
6 A. No.
7 MR. VAUGHN: Tyler, can we
8 go to, I think it's 2002, the
9 reliability of dietary data.
10 TRIAL TECH: I'm not seeing
11 that as a 2002 document.
12 MR. VAUGHN: I might have
13 the wrong -- give me one second.
14 2002-reliability of dietary.
15 (Document marked for
16 identification as Exhibit
17 Fryzek-24.)
18 TRIAL TECH: I'm not seeing
19 that on my end. Let me just
20 double-check that it was sent.
21 MR. VAUGHN: Let me drop it
22 in the chat, would that work?
23 TRIAL TECH: I've got it
24 here actually. Just give me one

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1 second and I can pull that up for
2 you.
3 You're good to go. Sorry I
4 missed that.
5 BY MR. VAUGHN:
6 Q. All right, Doctor. This
7 is -- you were the primary author on this
8 study, right?
9 A. Yeah. It was published in
10 2002.
11 Q. While you were at the --
12 A. 20 years ago.
13 Q. Do you think things have
14 changed since you published this?
15 A. I have no idea. I don't --
16 Q. Are you just letting me know
17 the year of it, or is there -- is there
18 something with the validity of it because
19 it's 20 years old?
20 A. I have no idea. It's just
21 going to be hard for me to remember,
22 so...
23 Q. All right. At the bottom of
24 it again, it says the funding was from

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1 the IEI.
2 I assume that you again have
3 no idea who actually provided the funding
4 to IEI for this study?
5 A. I believe it was just IEI,
6 because it was Dr. McLaughlin's
7 dissertation data.
8 Q. And under conclusion, you
9 found that "Dietary data collected
10 retrospectively from next-of-kin may be
11 unreliable," correct?
12 A. That's what the conclusion
13 says, but you have to read the whole
14 abstract to put it in context.
15 Q. Before that you noted that
16 "Overall, subjects tended to have better
17 agreement with their own earlier
18 reporting than did next-of-kin, and
19 spouses were found to be more reliable
20 next-of-kin respondents than older
21 relatives."
22 Do you still agree with that
23 statement?
24 A. It depends on what study

Page 230

1 you're talking about and where you're at.
2 Q. Why is that?
3 A. Pardon me?
4 Q. Why does it depend on what
5 study you're talking about?
6 A. Because this was done on a
7 case-control study. It could be a cohort
8 study. It depends on how they ask diet.
9 Q. But you agree that someone
10 giving them the report themselves is more
11 accurate than next-of-kin, correct?
12 MR. BALL: Objection to
13 form.
14 THE WITNESS: Usually yes.
15 Usually yes.
16 MR. VAUGHN: Then can we go
17 to Page 4, Tyler.
18 BY MR. VAUGHN:
19 Q. In the right-hand paragraph
20 notes, "Associations between food
21 preparation methods and specific cancers,
22 particularly lung and colorectal cancer,
23 have been demonstrated in some
24 epidemiologic studies."

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1 Did I read that correctly,
2 Doctor?
3 A. Yes.
4 Q. And then that "cooking time
5 and method may increase the formation of
6 certain cancer-causing compounds."
7 Did I read that correctly?
8 A. You did.
9 Q. And then the next sentence
10 is talking about meat preparation,
11 correct?
12 A. Yes.
13 Q. And so these associations on
14 how food is cooked and its risk of
15 increasing cancer, are you talking about
16 meat?
17 A. You know, I can't recall.
18 As I said, this has been more than
19 20 years ago. I can't recall.
20 Q. Do you agree that there are
21 associations between food preparation
22 methods and cancers, particularly lung
23 and colorectal cancer?
24 A. Again, it's not something

Page 232

1 I've looked at in over 20 years. So I
2 have no idea.
3 Q. Do you have any reason to
4 disagree with what you published earlier?
5 A. Again, I don't know what to
6 say the research is now. Epidemiology --
7 because all scientific research changes
8 over time. So I don't know.
9 Q. Were you not evaluating all
10 of that when you were forming your
11 opinions in this case?
12 MR. BALL: Objection to
13 form.
14 THE WITNESS: I guess I'm
15 not quite clear what you're
16 asking.
17 BY MR. VAUGHN:
18 Q. Well, I thought a big part
19 of your expert report was about dietary
20 intake of nitrosamines and if they
21 increase the risk of cancer in various
22 organs. Did you not look back over these
23 types of studies?
24 A. I looked at all studies of

Page 233

1 diet and NDMA's.
2 Q. And doesn't meat that's been
3 cooked have nitrosamines in it?
4 A. I believe it does, yes.
5 Q. And are you aware if the
6 more it's cooked or how it's cooked it
7 can increase the level of nitrosamines?
8 A. I'm sorry, I'm not clear
9 about that.
10 Q. You didn't look into how
11 food is cooked, if it impacts the levels
12 of nitrosamines?
13 A. If the study reported on it
14 we did.
15 Q. But you didn't do any
16 independent research?
17 A. No. This was a -- this was
18 a systematic narrative literature. We
19 didn't do any kind of research on this.
20 Q. And then you cite 11 through
21 14. And so those are studies that you
22 would agree support that certain food
23 preparation methods can increase the risk
24 of lung and colorectal cancer?

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1 A. Oh, I'd have to look at the
 2 studies.
 3 Q. Why would you have cited
 4 those studies?
 5 A. Again, it's over 20 years
 6 ago. So we'll have to look at them and
 7 see what they say.
 8 Q. Why do you normally cite
 9 studies?
 10 A. Because they support your
 11 statement.
 12 MR. VAUGHN: Can we go to
 13 his expert report now, Tyler.
 14 Give me just a minute to see
 15 where I want to go.
 16 Let's go to Page 21.
 17 BY MR. VAUGHN:
 18 Q. At the top you say, "Cohort
 19 studies have not demonstrated that NDMA
 20 or NDEA and diet are associated with any
 21 cancer type."
 22 Are you saying that none of
 23 the studies showed an association?
 24 A. Well, again, you can't just

Page 235

1 look at an individual study. You have to
 2 look at the totality of the evidence.
 3 Q. I understand that, but I'm
 4 just trying to understand this sentence
 5 where it says cohort studies have not
 6 demonstrated. Are you saying that no
 7 cohort study or the totality of them?
 8 A. Totality. Absolutely.
 9 Q. And so --
 10 A. And you can see that -- you
 11 can see that in the graphs that I made.
 12 It's easy to see. It's on page --
 13 Figure 3.
 14 Q. How do you define totality?
 15 A. How do I define totality?
 16 All of them. We look at them all
 17 combined. Include them all combined.
 18 Q. And so if they all do not
 19 show an association, you do not have a
 20 totality of evidence?
 21 A. You have to look at them all
 22 and make an assessment based on all of
 23 them.
 24 If you look at Figure 3 in

Page 236

1 my report, you can see graphically that
 2 none of them really are excessive --
 3 Q. What's your definition -- I
 4 apologize. What's your definition of
 5 excessive?
 6 A. Excessive, so what we've
 7 done is we've graphed -- we put on the Y
 8 axis one, which is no association, which
 9 made an exposed group and unexposed
 10 group.
 11 And then two, which means
 12 it's more likely than not. And so all of
 13 them have a confidence interval or a
 14 relative risk or hazard ratio or
 15 something that is two or less.
 16 Q. Why is two more likely than
 17 not?
 18 MR. BALL: Objection to
 19 form.
 20 THE WITNESS: People --
 21 BY MR. VAUGHN:
 22 Q. You said two would be more
 23 likely than not. What do you mean by
 24 that?

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1 A. Right. Relative risk of
 2 two.
 3 Q. Why does it need to be two
 4 to be more likely than not?
 5 A. I believe that's what the
 6 courts have agreed as more of a
 7 litigation definition.
 8 Q. So outside of legal
 9 definitions, what would be more likely
 10 than not in epidemiology?
 11 A. Oh, two. Relative risk or
 12 risk measure of two.
 13 Q. And what does two represent?
 14 A. Pardon me?
 15 Q. What does the two represent?
 16 Is that like a doubling of the risk?
 17 A. Yes.
 18 Q. Why do you need a doubling
 19 of the risk to be more likely than not?
 20 A. Because then you are less
 21 likely to have influence of confounders,
 22 bias, things like that.
 23 Q. So you're less likely, but
 24 just because you're below two, doesn't

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1 mean that it's not more likely than not,
2 correct?
3 MR. BALL: Objection to
4 form.
5 THE WITNESS: I'm not sure.
6 BY MR. VAUGHN:
7 Q. Why aren't you sure? Is
8 that outside of your area of expertise?
9 A. No. It depends on the study
10 you're looking at. It's really study
11 specific.
12 Q. So some studies you could
13 have a relative risk less than two and it
14 still be more likely than not?
15 A. I don't believe so. But
16 you'd have to show me the studies before
17 I could make a confirmatory response.
18 Q. Okay. A second ago, you
19 said it depends on the study. But now
20 you're saying you don't think there's
21 ever a time when below two would be more
22 likely than not?
23 A. What I'm saying is I just
24 don't know.

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1 Q. Okay. So Number 45, section
2 of that page.
3 A. Okay.
4 Q. All right. At about
5 two-thirds of the way down it says, "An
6 increased risk of colorectal cancer was
7 observed at the highest quartile of NDMA
8 intake compared to the lowest."
9 And then 2.12. What's that
10 2.12? What does that signify?
11 A. That is an adjusted relative
12 risk.
13 Q. This relative risk is above
14 two, correct?
15 A. Yes. And the confidence
16 interval is below two.
17 Q. And goes all the way up to
18 4.3, correct?
19 A. 1.04 to 4.33, yeah.
20 Q. And what's the 1.04
21 indicate?
22 A. The lower level of the
23 confidence interval.
24 Q. So that would be a 4 percent

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1 increased risk of cancer is the lowest?
2 A. Right.
3 Q. And so this didn't show any
4 discrepancy or ambiguity of if it would
5 increase the risk of cancer, did it?
6 A. I'm sorry?
7 Q. This --
8 MR. BALL: Objection to
9 form.
10 BY MR. VAUGHN:
11 Q. This study with the range of
12 1.04 to 4.33 in regards to colorectal
13 cancer with NDMA exposure, there's no
14 ambiguity about it increasing the risk,
15 is there?
16 A. Oh, we have to look at the
17 whole study. We have to look at
18 potential confounders they controlled
19 for, sample size, what it represents,
20 there's a lot of factors besides just the
21 confidence interval to statistical
22 significance of a study that shows
23 causality.
24 Q. Can you --

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1 A. A lot of things have to
2 be --
3 Q. I kind of read through this
4 Number 45. Can you show me where your
5 critiques are on the study?
6 A. So what we could take here,
7 it shows in the graph that the confidence
8 interval is less than two.
9 Q. I thought --
10 A. The relative risk --
11 Q. I thought it says 2.12.
12 A. That's not the confidence
13 interval. That's the -- that's the
14 estimate.
15 Q. And so you're saying if any
16 part of the confidence -- if any part of
17 the lower bound of the confidence
18 interval is under two, it doesn't count?
19 A. I'm not saying it's not more
20 likely than not. So you can see that in
21 our graph.
22 Q. But the lowest end of the
23 confidence interval is 1.04. The lowest
24 end is still showing a four percent

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1 increased risk, correct?
2 A. Correct.
3 Q. How is that not more likely
4 than not that it's increasing the risk of
5 colorectal cancer?
6 A. Because the definition of it
7 has to be 2.2.
8 Q. Whose definition?
9 A. Legal definition.
10 Q. You're not an attorney, are
11 you?
12 MR. BALL: Objection to
13 form.
14 THE WITNESS: I am not.
15 BY MR. VAUGHN:
16 Q. Going forward, when we do
17 definitions, can you give me definitions
18 from your area of expertise?
19 MR. BALL: Objection to
20 form. Considering the fact that
21 you asked him to identify things
22 as a toxicologist and a number of
23 other areas, I think that's a
24 little bit sly.

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1 MR. VAUGHN: Okay. Can you
2 just not give legal opinions?
3 How about that, Rick? Does
4 that work for you?
5 MR. BALL: That works for
6 me.
7 MR. VAUGHN: I appreciate
8 the clarification.
9 THE WITNESS: There's other
10 aspects that you have to look at.
11 The lower two quartiles didn't
12 show any -- quartiles, I'm
13 sorry -- didn't show any relative
14 risk, and there's no
15 dose-response. So it's likely to
16 not be causality.
17 BY MR. VAUGHN:
18 Q. So the lower levels didn't
19 show an increased risk but the higher
20 levels did show an increased risk. And
21 your opinion is that's not a
22 dose-response?
23 A. It shows that it's not a
24 dose-response. The P-value is greater

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1 than the .05.
2 Q. Do you agree that the higher
3 amounts of NDMA were associated with
4 cancer and the lower amounts of NDMA were
5 not?
6 A. They weren't statistically
7 significantly associated at the lowest.
8 At the highest level, yes.
9 Q. And what was the mean daily
10 NDMA intake in the diet in this study?
11 Do you see that?
12 A. Yeah. In the diet was
13 .052 micrograms.
14 Q. Micrograms. Do you know
15 what that would be in nanograms?
16 A. No. No, I don't.
17 Q. You don't know how many
18 nanograms are in a microgram?
19 A. No.
20 Q. You didn't look into that at
21 all when you were doing your expert
22 report?
23 A. It wasn't important to my
24 conclusions.

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1 Q. Do you think there might be
2 a thousand within it?
3 MR. BALL: Objection.
4 BY MR. VAUGHN:
5 Q. Micrograms. Do you think
6 that might be right?
7 A. I think it is. But I'm not
8 100 percent sure.
9 Q. But if it was a thousand,
10 would that mean that this is 52
11 nanograms?
12 A. Yes. If it was a thousand,
13 yes.
14 Q. And then when you add beer,
15 that subgroup got up to, I guess, 71
16 nanograms?
17 A. Yes. Yes.
18 Q. And so the differences
19 between these groups is just tens of
20 nanograms, right?
21 MR. BALL: Objection to
22 form.
23 THE WITNESS: What?
24

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1 BY MR. VAUGHN:
 2 Q. Tens of nanograms.
 3 A. So the mean daily NDMA
 4 intake includes beer. I don't quite
 5 understand what you're doing.
 6 Q. Oh, I'm reading what you
 7 have here. The mean daily NDMA intake
 8 from diet was 52 nanograms and
 9 specifically from beer was estimated in a
 10 subgroup at 71 nanograms.
 11 A. Okay.
 12 Q. And so the difference there
 13 is just like about 20 nanograms, right?
 14 A. Yeah, I am not quite sure
 15 what you're doing. Because the mean
 16 daily intake includes beer as well as
 17 everything. So I'm not quite sure what
 18 you're doing.
 19 Q. Okay. What was the highest
 20 exposure daily to NDMA in this group?
 21 A. I don't know.
 22 Q. You didn't --
 23 A. You know, you know, this is
 24 a Finnish diet too. I don't know how --

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1 how applicable this is to a U.S. diet.
 2 Q. What do you think is
 3 different?
 4 A. I have no idea. You have to
 5 look at that. And also, this is a diet
 6 back to 1999, so -- actually it does --
 7 66 to 72. So...
 8 That's one of the important
 9 things with epidemiology. You have to
 10 understand not only the statistical
 11 significance, the diet but how
 12 representative your data is. I'm not
 13 sure how representative this is of a U.S.
 14 population taking valsartan.
 15 Q. Do you think a U.S.
 16 population is exposed to less than
 17 52 nanograms in their diet a day?
 18 A. Oh, I have no idea.
 19 Q. You didn't look into that,
 20 did you?
 21 A. No.
 22 Q. Do people from Finland, do
 23 they process NDMA differently, do they
 24 metabolize it differently?

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1 MR. BALL: Objection to
 2 form.
 3 THE WITNESS: I have no
 4 idea -- I have no idea.
 5 BY MR. VAUGHN:
 6 Q. Do you have any reason to
 7 believe that people in Finland will
 8 metabolize NDMA differently than people
 9 in the United States?
 10 MR. BALL: Objection to
 11 form.
 12 THE WITNESS: I don't
 13 have -- I don't have any reason to
 14 believe that or not.
 15 BY MR. VAUGHN:
 16 Q. So as far as the levels of
 17 NDMA causing cancers in people in
 18 Finland, that should still be applicable
 19 to the United States, correct?
 20 MR. BALL: Objection to
 21 form.
 22 THE WITNESS: No.
 23 BY MR. VAUGHN:
 24 Q. Setting diet aside, I'm not

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1 saying how much we eat. I'm just saying,
 2 if we were exposed to the same amount of
 3 NDMA as people in Finland, would you not
 4 expect the same result?
 5 A. That I have no idea.
 6 Because also you have to look at the age
 7 group, the gender, things like that. You
 8 have to look at all the factors.
 9 MR. VAUGHN: Can you go to
 10 the next page, Tyler.
 11 BY MR. VAUGHN:
 12 Q. Earlier you were talking
 13 about dose-response and how the last
 14 study you didn't think really showed a
 15 dose-response.
 16 On Number 40 --
 17 A. It wasn't --
 18 Q. Huh?
 19 A. I just want to be clear. It
 20 wasn't my conclusion. It's the study's
 21 conclusion of a P-value greater than .05.
 22 Q. Well, do you disagree with
 23 the study's conclusion?
 24 A. No. I'm just reporting what

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1 the study said. You said I decided. I
2 didn't decide.
3 Q. But you also agree on that
4 prior study, the high dose of NDMA was
5 associated with cancer compared to the
6 low dose of NDMA, correct?
7 A. I don't believe it was
8 compared to low dose. I can't remember
9 what the comparison was.
10 Q. Did the low dose of NDMA
11 cause an increased risk of cancer?
12 A. They didn't find an
13 increased risk of cancer.
14 Q. Did the high dose increase
15 the risk of cancer?
16 A. That is what they found,
17 yes. For one cancer type, but not for
18 all cancer types. We were just talking
19 about colorectal cancer.
20 Q. And so there was a response
21 to the higher dose, but there wasn't a
22 response to the lower dose, correct?
23 MR. BALL: Objection to
24 form.

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1 THE WITNESS: There's no --
2 there was no dose-response.
3 BY MR. VAUGHN:
4 Q. That wasn't my question.
5 Was there an increased --
6 scratch that.
7 Do you agree that there was
8 an increased risk with the high dose and
9 there was not an increased risk with the
10 low dose?
11 A. Correct.
12 Q. So Number 47, we go a little
13 bit more than halfway down within 47, in
14 multivariate models. What is a
15 multivariate model?
16 A. Has more than variable in
17 it. Age, gender.
18 Q. It notes "there was a trend
19 of increasing risk of stomach cancer with
20 increasing NDMA intake and a
21 dose-response trend was observed."
22 A. Mm-hmm.
23 Q. And then it says p-trend,
24 0.02. What does that mean?

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1 A. The trend is significant.
2 The P-value is less than .05.
3 Q. And so being lower than .05,
4 does that make it even stronger?
5 MR. BALL: Objection to
6 form.
7 THE WITNESS: It just says
8 it -- it just says it is or isn't.
9 BY MR. VAUGHN:
10 Q. Being less than .05 doesn't
11 make it more likely that the results are
12 accurate?
13 MR. BALL: Objection to
14 form.
15 THE WITNESS: I don't know
16 what you mean by accurate.
17 BY MR. VAUGHN:
18 Q. Does the P-value being less
19 than .05 increase the statistical
20 significance of the results?
21 A. No. That's not my
22 understanding.
23 Q. But going above the .05
24 decreases the statistical significance?

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1 A. Correct. It makes it
2 nonstatistically significant.
3 Q. Why does this only go one
4 direction, why would being even low or
5 not increase the statistical
6 significance?
7 A. I guess I'm a little bit
8 lost about what you're asking, I'm sorry.
9 Q. Okay. So you said above a
10 .05 P-value, it would not be
11 statistically significant.
12 A. Right.
13 Q. If you're below a .05, like
14 this .2, .02, would .02 be even more
15 statistically significant in the results
16 than a .05 P-value?
17 MR. BALL: Objection to
18 form.
19 THE WITNESS: It is
20 statistically significant. The
21 point verifies that statistical
22 significance.
23 BY MR. VAUGHN:
24 Q. I'm asking is it more

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1 statistically significant to have .02
2 versus .05?
3 MR. BALL: Object to form.
4 THE WITNESS: I guess we're
5 getting confused. Because we
6 don't use the word "more
7 statistically significant." We
8 just say statistically
9 significant.
10 I do want to point out.
11 When you evaluate this literature
12 you can't go through each study
13 and look at the positive aspects
14 of each study. You have to look
15 at the totality of the literature.
16 That's what we did in the graph.
17 BY MR. VAUGHN:
18 Q. Lower down you note,
19 "However, only the highest levels of
20 intake had statistically significant
21 increased risk."
22 Are you talking about
23 highest levels of intake of NDMA had a
24 significantly increased risk on the

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1 formation of cancer, is that what that
2 sentence is saying?
3 A. It's hard because you take
4 it out of context. Let me try to read
5 the paragraph.
6 I believe we are talking
7 about processed meat and bacon and pork.
8 Q. So you think this sentence
9 is talking about the highest levels of
10 that meat?
11 A. Correct.
12 Q. And that meat contains NDMA,
13 right?
14 A. That's what they say, yes.
15 Q. And so the highest levels of
16 the NDMA had statistically significant
17 increased risk. What type of risk are
18 you talking about there?
19 A. Of the relationship between
20 the food intake and whatever cancer that
21 would be met.
22 Q. And this was stomach cancer
23 again, correct?
24 A. Yes.

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1 Q. Let's look at Number 49.
2 So this is 11.4-year
3 follow-up.
4 Doctor, in your opinion, if
5 something is a carcinogen, how soon will
6 you start seeing cancers in the
7 population if they are exposed to it?
8 A. Oh, it depends on what the
9 carcinogen is.
10 Q. If it was the most potent
11 carcinogen you know, what would the
12 soonest be?
13 A. Well, that, I don't know.
14 Q. Can people develop cancer
15 from a carcinogen within a year?
16 MR. BALL: Objection to
17 form.
18 THE WITNESS: I'm not -- I
19 don't know. That, I don't know.
20 BY MR. VAUGHN:
21 Q. What about within two years?
22 MR. BALL: Objection to
23 form.
24 THE WITNESS: I don't know.

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1 BY MR. VAUGHN:
2 Q. Within six months?
3 MR. BALL: Same objection.
4 THE WITNESS: I don't know.
5 BY MR. VAUGHN:
6 Q. You didn't consider any of
7 that when you were reviewing all these
8 studies?
9 A. Consider what?
10 Q. Consider how long or how
11 soon someone can get cancer after being
12 exposed to a carcinogen?
13 A. Well, we considered the
14 totality of the evidence, not just the
15 individual studies.
16 Q. What is a lag time in a
17 study? What does the word "lag time"
18 mean?
19 A. Can you use it and I can
20 explain it to you?
21 Q. So after someone is exposed
22 to a carcinogen, if they had a lag of one
23 year in the study, what does that mean?
24 A. That's just a year that they

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1 don't count exposure in their exposure
2 assessment.
3 Q. I'm having a hard time
4 hearing you. Can you say that again?
5 A. Let me try to go -- I'll
6 hold this up. Does that help?
7 Q. I can hear you. Go ahead.
8 A. Okay. That's a -- that's a
9 time period where they don't consider the
10 exposure.
11 Q. Do they not --
12 A. So there's acute -- seems
13 like --
14 Q. Are they not considering --
15 A. -- units of dose.
16 Q. So the lag doesn't have to
17 do with if they were diagnosed with
18 cancer in that first year? It has to do
19 with dose?
20 A. Right. Well, no, not with
21 dose, with exposure.
22 MR. BALL: Objection.
23 BY MR. VAUGHN:
24 Q. The lag has nothing to do

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1 with what's counted as far as diagnoses?
2 A. It's --
3 MR. BALL: Objection to
4 form.
5 THE WITNESS: -- exposures.
6 BY MR. VAUGHN:
7 Q. Sorry. I'm having a hard
8 time hearing you over the objections.
9 All the transcript picked up was the word
10 "exposures."
11 A. So it deals with exposure.
12 You're talking about a lag exposure, not
13 a lag diagnosis.
14 THE COURT REPORTER: Can you
15 repeat that?
16 THE WITNESS: Not a lag
17 diagnosis.
18 BY MR. VAUGHN:
19 Q. At the bottom of 49 on that
20 Page 22, do you see what the main NDMA
21 levels were for cancer cases?
22 MR. VAUGHN: Sorry, yeah, on
23 Page 22 still. Bottom of -- yeah.
24

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1 BY MR. VAUGHN:
2 Q. 59 nanograms a day; is that
3 correct?
4 A. Yes. Yes.
5 Q. They do the conversion to
6 micrograms. And that's -- would be a
7 thousand, right?
8 A. Right.
9 Q. The conversion that we said
10 earlier.
11 And this one's in Norfolk,
12 UK. But they have a pretty similar
13 amount of exposure to NDMA as the
14 Finlands did, didn't they?
15 A. Oh, I don't know.
16 Q. Well, I mean, we looked
17 at --
18 A. This is -- this isn't
19 everyone in Norfolk, and not everyone in
20 Finland. So it's, you know, a cohort of
21 people. It's a group of people. And
22 each of those groups is not everyone. So
23 I have no idea.
24 Q. Their average amount of

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1 exposure is very similar to what the
2 people in Finland were exposed to,
3 correct?
4 A. It's not the people in
5 Finland. It's the people in Finland that
6 were in the study. I mean, I don't know
7 what the age group is of the people in
8 Finland. So we have to look at those
9 types of things too.
10 Q. And again, with this study,
11 we're noticing an increased risk of
12 cancer, are we not?
13 A. I don't know.
14 MR. BALL: Objection to
15 form.
16 THE WITNESS: I can read on
17 my --
18 MR. VAUGHN: Let's go to the
19 next page.
20 BY MR. VAUGHN:
21 Q. I can read it for you if
22 it's quicker.
23 A. Okay.
24 Q. "When NDMA intake was

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1 analyzed as a continuous variable, there
2 was a small statistically significant
3 increased cancer risk per unit increase
4 in NDMA intake in the full study
5 population."
6 Is that a dose-response when
7 it's saying per unit increase of NDMA?
8 A. Let me see. So this is as
9 each unit of NDMA goes up, then the
10 increase goes up slightly, yes.
11 Q. Is that known as a
12 dose-response?
13 A. This was looking at
14 continuous -- when this -- when you're
15 looking at continuous, you'd see this.
16 But when you're looking at, like,
17 quartiles you don't see it. So you have
18 to be careful.
19 Q. Is this known as a
20 dose-response?
21 A. I would consider that a
22 dose-response, yes. Again, you have to
23 be careful of your interpretation,
24 because you see it in men, but not in

Page 263

1 women. You can't understand that.
2 There's a lot of things, a lot of
3 questions in this study.
4 Q. Who do you think eats more
5 on average, meat; a male or female?
6 A. I'm sorry?
7 Q. Do you think a male or a
8 female eats more meat on average?
9 MR. BALL: Objection to
10 form.
11 THE WITNESS: I have no
12 idea.
13 BY MR. VAUGHN:
14 Q. How about drinking beer? Do
15 you think men drink more beer than women?
16 MR. BALL: Object to form.
17 THE WITNESS: I have no
18 idea.
19 BY MR. VAUGHN:
20 Q. Okay. And do you see a
21 little bit farther down, it also notes
22 that there was a statistically
23 significant association with rectal
24 cancer?

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1 A. Rectal -- when you analyzed
2 NDMA as a continuous variable, you see it
3 as rectal cancer, GI cancers, and other
4 cancers.
5 MR. VAUGHN: Let's go to
6 Number 50, Tyler.
7 THE WITNESS: I just want to
8 mention that you skipped over the
9 last sentence, which I think is
10 important.
11 BY MR. VAUGHN:
12 Q. Mm-hmm.
13 A. Can we read that?
14 Q. Your attorney will have a
15 chance to go back through anything that
16 you would like on his time?
17 MR. BALL: Jon, if you want
18 to read it, you feel free to read
19 it if you feel it helps explain
20 your answer.
21 THE WITNESS: The last
22 sentence, I think, is important.
23 It says that the limitations
24 of the study which is biases in

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1 the measurement error associated
2 with food frequency
3 questionnaires, multiple risk
4 factors -- and also multiple risk
5 factors that are not controlled
6 for in the analysis for specific
7 cancers.
8 BY MR. VAUGHN:
9 MR. VAUGHN: Move to strike.
10 There was --
11 THE WITNESS: You have to
12 look at all --
13 MR. VAUGHN: -- no question
14 on the table.
15 THE WITNESS: You have to
16 look at all those things when you
17 assess the study. You can't just
18 look at the statistical
19 significance.
20 MR. VAUGHN: Move to strike.
21 There is no question on the table.
22 MR. BALL: He was answering
23 your prior question. He hadn't
24 quite finished. He made that

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1 clear.
 2 MR. VAUGHN: All right. Let
 3 go and look at Number 50 now,
 4 Tyler.
 5 BY MR. VAUGHN:
 6 Q. Let's see. If we go a
 7 little more than halfway down this one
 8 actually notes that the median NDMA
 9 intake was much higher for men. It comes
 10 out to 80 nanograms, versus women,
 11 40-nanograms.
 12 Do you think that's probably
 13 consistent amongst most of the
 14 populations, that men are consuming more
 15 NDMA than women?
 16 MR. BALL: Objection to
 17 form.
 18 THE WITNESS: I have no
 19 idea.
 20 BY MR. VAUGHN:
 21 Q. Do you think the
 22 difference --
 23 A. -- look at all --
 24 Q. Do you think the

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1 difference --
 2 A. -- by populations.
 3 Q. Sorry, what did you say?
 4 A. That I haven't looked at all
 5 populations in the world to make a
 6 statement, the conclusion.
 7 Q. Do you think a difference in
 8 80 nanograms a day and 40 nanograms a day
 9 might explain why men have a more
 10 increased risk of cancer?
 11 MR. BALL: Objection to
 12 form.
 13 THE WITNESS: Oh, I have no
 14 idea. There's no relationship
 15 between NDMA and cancer -- to
 16 explain it.
 17 BY MR. VAUGHN:
 18 Q. None?
 19 A. No. The totality of the
 20 evidence.
 21 Q. Okay. So two sentences
 22 later, "In men, esophageal squamous cell
 23 cancer was associated with NDMA intake,"
 24 and then HR 2.43. What is HR?

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1 A. Hazards ratio.
 2 Q. And what is the difference
 3 of an HR and an RR?
 4 A. It's looking at -- it's a
 5 survival analysis versus a relative risk.
 6 Q. And then the confidence
 7 interval is 95 percent, right?
 8 A. Yes.
 9 Q. And then the -- the P-trend
 10 is .01. So that's below that .05 that
 11 you were saying we need, right?
 12 A. Correct.
 13 Q. And are you discounting this
 14 one because the lower end is 1.13?
 15 MR. BALL: Objection to the
 16 form.
 17 THE WITNESS: You have to
 18 look at all of them. You have to
 19 look at all the studies, you know,
 20 together. That's why we did the
 21 graphs.
 22 BY MR. VAUGHN:
 23 Q. I guess there is diet ones,
 24 okay.

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1 And your opinion is there's
 2 no strong evidence that NDMA and NDEA are
 3 associated with cancer, correct?
 4 MR. BALL: Objection to
 5 form.
 6 THE WITNESS: Where do you
 7 see that?
 8 BY MR. VAUGHN:
 9 Q. Page 24 of your report.
 10 A. So these studies -- the
 11 cohort studies state they are no
 12 associations with any cancer type.
 13 Case-control says there's no strong
 14 evidence that NDMA or NDEA is associated
 15 with cancer. So we separate it by the
 16 study designs.
 17 Q. Oh. So the studies we were
 18 looking at a second ago were the cohort
 19 studies?
 20 A. Yep, yes, sir. Yeah.
 21 Q. Ok. So that part of your
 22 opinion is, I guess, on Page 21 where you
 23 say "Cohort studies have not demonstrated
 24 that NDMA or NDEA in diet are associated

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1 with any cancer type."
2 And then all those studies
3 that we went through where there is an
4 association with a cancer type, those are
5 the ones that you are talking about?
6 MR. BALL: Objection to
7 form.
8 THE WITNESS: You're
9 misquoting my statement. You have
10 to -- you have to look at all the
11 studies combined. That's why we
12 did the graphs.
13 You can't just pull out a
14 single study and say that this is
15 statistically significant, so this
16 is an association. You have to
17 look at the totality of the
18 evidence.
19 BY MR. VAUGHN:
20 Q. Did I only discuss one study
21 with you?
22 A. Well, you discussed the
23 positive results of a few studies, yes.
24 Q. I mean you only have seven

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1 studies even here.
2 A. Okay. That's why we did the
3 graph so you can look at the graph and
4 see.
5 MR. VAUGHN: Let's go to
6 Page 24 now, Tyler. 52.
7 BY MR. VAUGHN:
8 Q. All right. So this one,
9 second line on the right was in Hawaii.
10 So this is a United States one, correct?
11 A. Let me see. Conducted in
12 Hawaii. Yes, in the '80s. Between '83
13 and '85.
14 Q. And do you have any reason
15 to believe that humans process NDMA
16 differently now than in '83 or '85?
17 A. I guess the more important
18 question is, are the diets similar in '83
19 and '85 as they are now.
20 Q. Why is that the more
21 important question?
22 A. Because the NDMA exposure
23 levels would be different. Also, the age
24 and all other confounders as well. So

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1 you have to understand the
2 representatives of the population.
3 Q. What if these NDMA exposure
4 levels are way below what's in valsartan?
5 MR. BALL: Objection to
6 form.
7 BY MR. VAUGHN:
8 Q. Would that -- would the
9 study not be very relevant to does the
10 NDMA in valsartan cause cancer?
11 A. I have no idea. You have to
12 show me an example of a study that looked
13 at that.
14 Q. If these studies are showing
15 an association with NDMA and cancer and
16 valsartan has even higher levels of NDMA,
17 would you not expect valsartan with NDMA
18 to be able to cause cancer as well?
19 MR. BALL: Object to form.
20 THE WITNESS: The totality
21 of the evidence isn't showing a
22 relationship with cancer.
23 BY MR. VAUGHN:
24 Q. All right. Midway through

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1 on this one where it says, "An
2 association between NDMA and risk of lung
3 cancer was observed for men in the
4 highest two categories of NDMA intake.
5 OR" --
6 And what is OR?
7 A. Odds ratio.
8 Q. And how is that different
9 than the HR and RR that we were talking
10 about?
11 A. Well, odds ratio is for a
12 case-control study. In a case-control
13 study you pick subjects based on the
14 disease status and then you look back in
15 time to see if they have exposure or not.
16 Which is the odds of having exposure in
17 the cases versus the odds of having
18 exposure in the controls.
19 Q. So we're seeing a 2.8 odds
20 ratio. And now that CI, it says 1.5 to
21 4.3. Does that mean that the levels were
22 getting five -- over five times more
23 cancer?
24 A. That's the -- that's the

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1 confidence interval. If you repeat the
2 study over and over again, 95 percent of
3 the time the S value would be between
4 1.5 and 4.3 -- so 1.4 and 5.3.
5 Q. So it would be increasing
6 the rate of cancer between 40 percent and
7 530 percent?
8 A. Correct. 95 percent of the
9 time.
10 Q. And then Q4, is that -- is
11 that the highest quartile? The other one
12 said Q3.
13 A. Yes.
14 Q. And so Q4, when they gave
15 even more NDMA, the odds ratio went from
16 2.8 to 3.3?
17 A. It does. Confidence
18 intervals overlap. So that tells you the
19 numbers aren't different.
20 Q. That confidence interval now
21 is up from -- up to 1.7 to 6.2, so at the
22 highest levels they are seeing 70 to
23 620 percent higher levels of cancer with
24 NDMA?

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1 A. Right. But it overlaps with
2 the Quarter 3 confidence intervals.
3 Q. And it says that this is a
4 strong dose-response trend. Do you see
5 that?
6 A. Yes. Yes.
7 Q. And then the P-trend is
8 .0006.
9 Is this a strong
10 dose-response trend because of the low
11 P-value or because of the high percent
12 increases in cancer?
13 MR. BALL: Objection to
14 form.
15 THE WITNESS: I would say
16 both. Well, the cancer increase
17 isn't high. I mean it's between
18 1.7 and 6.2, which overlaps with
19 the quarter -- Quartile 3
20 confidence interval.
21 MR. VAUGHN: We can go to
22 the next page Tyler.
23 BY MR. VAUGHN:
24 Q. This would be Number 53. We

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1 just can't see that number at the top.
2 At the top it says, "An association was
3 seen between NDMA intake and lung cancer
4 at third and highest quartiles," correct?
5 A. Correct.
6 Q. And earlier I think you were
7 talking about how some of these studies
8 weren't maybe controlled properly. This
9 one is actually controlled for age, sex,
10 residence, urban/rural status, family
11 history of lung cancer, BMI, pack years,
12 and total energy intake, correct?
13 A. Correct.
14 Q. And is this showing a
15 dose-response trend again where the third
16 quartile is increasing by 6 percent to
17 296 percent increased risk of cancer
18 while the highest quartile is
19 experiencing a 86 percent to 529 percent
20 increase of cancer?
21 A. I don't know if they
22 calculated a dose-response trend or not.
23 Q. Well, I mean, are we not
24 seeing higher rates of cancer as the dose

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1 goes up if we are seeing third quartiles
2 associated with cancer, the fourth
3 quartile is associated with even higher
4 cancer and it looks like the first two
5 were not?
6 A. Yeah, so what you also have
7 to look at is the confidence interval.
8 So if the first confidence
9 interval goes from 1.06 to 2.96, and the
10 confidence interval for the highest
11 quartile goes from 1.86 to 5.29, those
12 confidence intervals overlap.
13 Q. But they also remain
14 higher --
15 A. I'm not sure if it's
16 statistically different or not. That's
17 why I would need the P-value to look at
18 that.
19 Q. You agree that the first two
20 quartiles to the lowest amounts of NDMA
21 were not associated with an increased
22 risk of cancer, correct?
23 A. Well, I'd have to look at
24 that and see. I don't -- it's not

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1 represented on this page that you're
2 showing me.
3 Q. What are your critiques on
4 this study?
5 A. Let me look at my written
6 copy of my printed-out copy here so I can
7 see. This is Paragraph 52 or 53?
8 Q. 53.
9 A. It looks like some of the
10 results were inconsistent. We'd have to
11 look at the paper to see exactly what it
12 is. Some of the results are
13 inconsistent.
14 Q. What results are you talking
15 about?
16 A. At the end. The results
17 about NDMA-containing food, et cetera.
18 They don't seem consistent the high risk.
19 Also, it is also a hospital-based
20 case-control study, which there's concern
21 about using hospital controls. So the
22 study design is problematic as well.
23 Q. The food that it was
24 associated with an increased risk of

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1 cancer is also the food that has the
2 highest NDMA concentration, correct?
3 MR. BALL: Object to form.
4 THE WITNESS: That's right.
5 But the risk was really small. It
6 was borderline statistically
7 significant, which is 1.01. None
8 of the other with high estimated
9 NDMA levels had an association or
10 an increased risk.
11 BY MR. VAUGHN:
12 Q. So then 54, it looks like
13 you -- you only have three studies cited
14 under lung cancer, the two that we just
15 went over, then you cite Loh. And so are
16 you use Loh to invalidate the other two
17 results?
18 A. We reported on all the
19 studies we find.
20 Q. Well, you're saying that you
21 don't think that the diet or NDMA and
22 NDEA are associated with increased risk
23 of cancer. And the only three that you
24 discuss on lung cancer are these three.

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1 And you're coming out and saying it
2 doesn't increase the risk. And so are
3 you basically using Loh to basically say
4 these other two studies can't be right?
5 A. No. I'm saying the other
6 two studies have problems with them as
7 well. Methodological problems.
8 Q. And what are those
9 methodological problems?
10 A. Methodological problems I
11 said.
12 Q. Yeah, what are they?
13 A. The first one uses a lot of
14 proxy respondents.
15 Q. What is a proxy respondent?
16 A. It's what you showed my
17 paper on, where we compared
18 self-respondents to proxy respondents,
19 and you showed the proxy respondents
20 weren't very good. So this supports
21 that.
22 Q. What about the other study?
23 A. Yeah, it wasn't consistent
24 across the different food groups.

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1 Q. But not all the food groups
2 had the same level of NDMA in it, right?
3 A. Right. But you would expect
4 some risk. And you don't see any risk at
5 all.
6 Q. But the highest levels, you
7 do?
8 A. If there's an association.
9 But as I said, I don't believe in the
10 association. The studies don't show
11 there's an association with any cancer.
12 Q. It literally says, "An
13 association was seen between NDMA intake
14 and lung cancer at the third and highest
15 quartiles." It's at the top of the page
16 of your report.
17 A. Right. That sentence
18 doesn't -- doesn't describe what -- the
19 totality of the studies, right?
20 Q. Tell me if it's --
21 A. If you look -- if you look
22 at my -- if you look at my figure, that
23 helps you, so you don't have to look at
24 individual studies.

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1 Q. But I'm trying to understand
2 what you think is wrong with individual
3 studies and why you think certain ones
4 are stronger.
5 A. I don't even say that when I
6 graph them. When you look at the graph,
7 you can see where all the studies fall.
8 Overall, case-control studies with diet
9 are hard to understand because you're
10 picking people after they have the
11 disease, and that may make them report or
12 remember what was in their diet
13 differently.
14 Q. That's something actually I
15 want to talk about. Why is that?
16 A. Why is it? Because people
17 try to figure out why they had cancer.
18 Q. And to that end, wouldn't
19 they have to know that NDMA is associated
20 with cancer for it to influence their --
21 A. Right, so but here they're
22 not asking about NDMA. They're asking
23 about different food stuff, et cetera.
24 Q. So wouldn't they have to

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1 know that certain foods are associated
2 with increased risk of cancers for it
3 bias their answers?
4 A. Well, I think at this time
5 people knew that there was certain foods
6 that were, you know, not as good for you.
7 Q. What do you mean by not as
8 good for you?
9 A. You don't see any vegetables
10 or fruit.
11 Q. What do you mean by that,
12 you don't see any vegetables or fruit?
13 A. There's no increased risk
14 for those groups.
15 Q. Why do you think that is?
16 A. Because they didn't report
17 it.
18 Q. And so you think people know
19 that salted meat, salted fish, barbecue
20 has enough carcinogens in it to increase
21 their risk of cancer and is going bias
22 their answers? That's what you think?
23 MR. BALL: Objection to
24 form.

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1 THE WITNESS: I think that
2 those people realize that those
3 aren't foods that they should have
4 eaten all the time.
5 BY MR. VAUGHN:
6 Q. And so you think that
7 they're going to associate that with
8 their cancer and say they eat more of it?
9 A. I think people that are ill,
10 you know, remember things like that more
11 than people that aren't ill, will overly
12 report those things.
13 Q. So people that are ill say
14 that they eat more bacon than they
15 actually do?
16 A. Maybe.
17 MR. BALL: Objection to
18 form.
19 BY MR. VAUGHN:
20 Q. Do people frequently
21 exaggerate how much alcohol they drink
22 when they're reporting it?
23 A. You'd have to look at the --
24 individual studies have, you know,

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1 different results. So you have
2 different -- some measures of validity in
3 the study.
4 Q. Do you think these people
5 that are filling out these questionnaires
6 are, like, planning on suing a company
7 that makes bacon or something?
8 MR. BALL: Object to form.
9 BY MR. VAUGHN:
10 Q. What's their incentive for
11 lying on these questionnaires?
12 MR. BALL: Object to form.
13 THE WITNESS: I didn't
14 say they -- I didn't say they were
15 lying. I didn't say they had
16 incentives. I said they were just
17 trying to figure out why they have
18 cancer.
19 When I did my -- when I did
20 my dissertation, I interviewed
21 people myself that had pancreatic
22 disease. It was a tough disease,
23 and they were trying to figure out
24 why the heck they had it. They

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1 died within a month --
2 BY MR. VAUGHN:
3 Q. I was going to say --
4 A. -- of being diagnosed.
5 Q. -- people with pancreatic
6 cancer don't have much time to figure out
7 what caused it, do they?
8 A. But they think a lot about
9 it, much more than a person without
10 cancer.
11 Q. You think that means that
12 they recall more accurately or that they
13 exaggerate?
14 MR. BALL: Objection to
15 form.
16 THE WITNESS: It depends on
17 the study. It depends on the
18 population. It depends on what
19 you're asking. It depends on a
20 lot of stuff.
21 It's something that you
22 should try to assess in your
23 studies.
24 MR. VAUGHN: Rick, I know we

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1 haven't been going for a ton of
2 time, but I drank a bunch of
3 coffee at lunch. Do you mind if
4 we take a break already?
5 MR. BALL: That's fine.
6 THE VIDEOGRAPHER: Off the
7 record, 2:01 p.m.
8 (Short break.)
9 THE VIDEOGRAPHER: We are
10 back on the record at 2:09 p.m.
11 BY MR. VAUGHN:
12 Q. Let's go to stomach cancer,
13 Number 55. And let's go to Page 26 at
14 the top of the page.
15 MR. VAUGHN: The top part,
16 sorry, where it's continuing on
17 from 55. Yeah.
18 BY MR. VAUGHN:
19 Q. The sentence starting with
20 however, the second sentence. Can you
21 read the sentence aloud for us, Doctor?
22 A. "However, stomach cancer
23 risk was increased with increasing smoked
24 meat, a food high in NDMA, after

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1 adjusting for other food groups, total
2 food consumption and ethnicity."
3 Q. And then where we have this
4 1.76-8.75, is that saying the upper end
5 was increasing the risk of stomach cancer
6 by 875 percent?
7 A. The confidence interval went
8 from 1.76 to 8.75, yes.
9 Q. To the 76 percent increased
10 risk to an 875 percent increased risk?
11 A. Yes.
12 Q. On number --
13 A. -- that's assessing for food
14 groups, total food consumption, and
15 ethnicity. It didn't adjust for every
16 potential risk factor for stomach cancer,
17 like H. pylori. So it is a limitation.
18 Q. Do you have reason to
19 believe that one group had a higher rate
20 of H. pylori than the other group?
21 A. Yeah. There is a
22 relationship between stomach cancer and
23 H. pylori.
24 Also, as I note here, you

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1 have to take -- be mindful of the
2 limitations of the study. Response rate
3 was low, it was only 44 percent. Usually
4 we like it above 60 percent in
5 case-control studies. And they had to
6 get rid of a third of the case because
7 they died or had severe illness. You
8 have to get your cases as quickly as you
9 can after they're diagnosed.
10 My pancreatic cancer
11 studies, but I like -- I went daily to
12 pathology departments to look for people
13 who had pancreatic cancer, was able to
14 get to them within two weeks. It looks
15 like they had a longer time period.
16 Q. Is it problematic if a study
17 is excluding a third of the patients that
18 get cancer?
19 MR. BALL: Objection to
20 form.
21 THE WITNESS: Oh, very much
22 so. You're not getting a
23 representative sample of your
24 cases.

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1 BY MR. VAUGHN:
2 Q. I missed the first part of
3 your answer with that objection. I'm
4 sorry, did you say, "Very much so"?
5 A. Absolutely, yes.
6 Q. And why is --
7 A. You really got to -- you
8 really got to try to get everyone you can
9 before they are dead. Because it could
10 be that the exposure leads to early
11 death. You don't know. You don't have
12 those people in your study.
13 Q. So a study that is
14 evaluating the risk of cancer, you
15 wouldn't want to get rid of one-third of
16 the people that ended up getting cancer,
17 correct?
18 A. Correct. You want to try to
19 get your response rate as high as you
20 can, so...
21 Q. Because if a third of the
22 people were excluded that got cancer,
23 that could really invalidate the results,
24 correct?

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1 A. You just don't know unless
2 you do another research study to figure
3 that out.
4 Q. So that study alone wouldn't
5 be reliable, you would need at least
6 another study to confirm it?
7 A. I would, yes. Very much so.
8 I think I -- oh, I actually say that in
9 the last sentence. "The included cases
10 may represent earlier or less severe form
11 of the disease." That's a problem.
12 Q. Because the people with a
13 severe disease could have died really
14 quickly, right?
15 A. Correct.
16 Q. Something like pancreatic
17 cancer, that can kill you within a month
18 or two, right?
19 A. Yeah. As I said, that's why
20 I tried to get to people as quickly as I
21 could, within two weeks.
22 Q. What other cancers can kill
23 you really quickly besides pancreatic
24 cancer? Are there other ones that are

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1 kind of known for that?
2 A. I'm trying to think. Off
3 the top of my -- off the top of my head I
4 can't recall. Pancreatic cancer is the
5 one that is mostly known. The other ones
6 I'm not sure.
7 MR. VAUGHN: Tyler, let's
8 take a break from the report for
9 just a second, and let's go to
10 2021 Gomm.
11 (Document marked for
12 identification as Exhibit
13 Fryzek-25.)
14 BY MR. VAUGHN:
15 Q. Do you remember the Gomm
16 study, Doctor?
17 A. Yeah, I believe that is the
18 German valsartan study?
19 Q. Yeah, using the insurance
20 data from Germany, right?
21 A. Yes. Yes, sir.
22 Q. And you don't know if this
23 insurance company has any relationship to
24 any of the defendants, do you?

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1 A. Oh, I have no idea.
2 MR. VAUGHN: Tyler, can we
3 go to Page 8.
4 BY MR. VAUGHN:
5 Q. Did you review this part of
6 the study, Doctor, the selection criteria
7 when you were forming your opinions?
8 A. Yeah, I did read it.
9 Q. And so patients who were
10 continuously insured by AOK during the
11 years 2009 to '13 were included in this
12 study, correct?
13 Do you see that under
14 Selection Criteria?
15 A. Yes.
16 Can we make this a little
17 bit bigger? Thank you.
18 MR. VAUGHN: Thank you,
19 Tyler.
20 BY MR. VAUGHN:
21 Q. The valsartan contamination
22 continued on well past 2013, correct?
23 A. Where do you see that?
24 Q. Are you aware of the years

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1 that valsartan was contaminated with
2 NDMA?
3 A. I'm not aware of the years
4 in Germany. But I believe this article
5 says so. Let me look.
6 Q. Go ahead. Are you able to
7 download it and let me know?
8 A. Oh, you want me to download?
9 Q. Or if you go to Page 1 it
10 notes that in Germany the Federal
11 Institute for Drugs and Medical Devices
12 ordered a recall of drug products
13 contaminated with NDMA in July of 2018.
14 So would you think then that
15 in two thousand -- go ahead.
16 A. No. Well, in the methods
17 section they define how they determine
18 who was exposed with valsartan and who
19 was not exposed. So if you go to the
20 methods section that will tell us.
21 Q. So --
22 A. If that's the method in the
23 abstract, that's not right.
24 Q. I'm asking you -- there was

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1 contaminated valsartan on the market in
2 Germany after 2013, correct?
3 A. But I'd like to look at the
4 methods because then we'd be clear.
5 Otherwise, I'm just kind of trying to
6 remember.
7 Q. Okay.
8 MR. VAUGHN: Go ahead and
9 pull the methods section up there
10 for him.
11 BY MR. VAUGHN:
12 Q. "Cohort comprised patients
13 who filled a prescription of valsartan
14 from the period of 2012 to 2017."
15 A. Okay.
16 Q. Does that help you? It's on
17 Page 1 it notes it too. Yeah.
18 A. If you just go down. I
19 think it's the next sentence.
20 "Potential NDMA
21 contamination was assessed on the basis
22 of pharmaceutical registration number."
23 So it looks like they looked
24 for specific pharmaceutical registration

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1 numbers between that time, 2012 and 2017.
2 Q. Which is after 2013,
3 correct?
4 A. 2012 isn't.
5 Q. Okay. So some of it was
6 before.
7 But, again, their selection
8 criteria for patients who were
9 continuously insured on the years 2009 to
10 2013, correct?
11 A. I believe that's the year,
12 yeah.
13 Q. Ok. If we go back to
14 page --
15 A. It's hard -- it's hard to
16 remember.
17 MR. VAUGHN: Or Page 8, I
18 guess is what we were on, Tyler.
19 BY MR. VAUGHN:
20 Q. If someone lost their
21 insurance after 2013, their cancer
22 diagnosis is not going to be captured, is
23 it?
24 A. Correct.

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1 Q. Or if they changed
2 insurances from AOK, it's not going to be
3 captured either, is it?
4 A. You know, I'm not -- I'm not
5 aware of the insurance system in Germany.
6 I don't know how it operates.
7 Q. Did you not look into that
8 at all --
9 A. What you're saying --
10 Q. -- when you were
11 evaluating --
12 A. What you're say -- what
13 you're saying is true for the U.S. So if
14 they have more than one insurance group,
15 you know, I just don't know.
16 Q. All right. In the second
17 paragraph, it notes, "For outpatient
18 diagnosis, at least one confirmatory
19 diagnosis within the following four
20 quarters was required for validation."
21 Were you aware of that?
22 A. That's what it says, yes.
23 Q. Is that normal to do?
24 MR. BALL: Objection to

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1 form.
2 THE WITNESS: I don't know
3 if it's normal in Germany. I
4 don't know -- I don't know how
5 patients interact -- interact with
6 the healthcare system in Germany,
7 so.
8 BY MR. VAUGHN:
9 Q. When you do studies, do you
10 confirm confirmatory diagnosis?
11 A. Typically if you do studies
12 of these type of claims data, you try to
13 get -- look at two diagnoses, yes,
14 because you don't want -- if you just
15 look at one diagnosis, you run the risk
16 of getting a rule-out diagnosis.
17 So they just report
18 something to insurance to see if they can
19 rule it out or not. They're not sure
20 that it's actually cancer.
21 Q. So was it improper for the
22 other cancer patients that weren't
23 outpatient for them to only require one
24 diagnosis?

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1 MR. BALL: Objection to
2 form.
3 THE WITNESS: You mean
4 inpatients?
5 BY MR. VAUGHN:
6 Q. Yeah.
7 A. No. That's pretty popular
8 to do that. So outpatient you need two.
9 Inpatient you need one.
10 Q. So if someone went and got
11 an outpatient diagnosis of cancer, went
12 back home, blew their brains out, they're
13 not going to get included in this study,
14 are they?
15 MR. BALL: Object to form.
16 THE WITNESS: Right. No.
17 BY MR. VAUGHN:
18 Q. Or someone --
19 A. I have no idea how often
20 that happens. I can't imagine that
21 happens much.
22 Q. You don't think people --
23 A. You're trying to
24 discredit --

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1 Q. You don't think people get
2 diagnosed with cancer and they're so
3 upset they kill themselves?
4 MR. BALL: Object to form.
5 THE WITNESS: I have no -- I
6 have no data. I've never seen any
7 data.
8 BY MR. VAUGHN:
9 Q. You're not aware of any of
10 the plaintiffs in this litigation have
11 killed themselves because of their cancer
12 diagnosis?
13 MR. BALL: Object to form.
14 THE WITNESS: I have no
15 knowledge of that. No knowledge
16 of that.
17 BY MR. VAUGHN:
18 Q. And so also if someone got
19 an outpatient diagnosis, quit their job,
20 lost their insurance, they're not going
21 to be included in this study, are they?
22 MR. BALL: Object to form.
23 THE WITNESS: Yeah, they
24 would if they had a cancer

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1 diagnosis while they had
2 insurance.
3 BY MR. VAUGHN:
4 Q. If they -- if they quit
5 their job and lost their insurance, they
6 wouldn't get captured in this, would
7 they?
8 MR. BALL: Object to form.
9 THE WITNESS: It depends --
10 it depends on whether a cancer
11 diagnosis was made. If they quit
12 their job and lost their
13 insurance, they wouldn't have any
14 way to get to a physician to get
15 medical care. I'm confused by
16 your question.
17 BY MR. VAUGHN:
18 Q. I mean, they could still --
19 they could still get a different
20 insurance or they could pay out of
21 pocket, could they not?
22 MR. BALL: Object to form.
23 THE WITNESS: I have no
24 idea. This is a German healthcare

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1 system. I have no idea.
 2 BY MR. VAUGHN:
 3 Q. Further down in that
 4 paragraph it notes, "Persons with other
 5 cancer diagnosis before the index quarter
 6 in which the examined cancer diagnosed
 7 were not included in the analysis for
 8 specific individual cancer types."
 9 Does that mean if someone
 10 got a diagnosis outpatient and then a
 11 different cancer diagnosis inpatient,
 12 that they would not be included?
 13 MR. BALL: Object to form.
 14 THE WITNESS: Let me read
 15 it -- let me read it again.
 16 They were included -- I
 17 think that what they are saying,
 18 and this is just my guess of what
 19 they're saying, is if a person is
 20 diagnosed with two different types
 21 of cancer, they weren't included
 22 in the individual cancer types,
 23 but they're included in the
 24 analysis with all the cancer,

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1 which is commonly done.
 2 BY MR. VAUGHN:
 3 Q. Where do you draw the
 4 inference that they were included for the
 5 all cancer?
 6 A. It says they were not
 7 included in the analysis for a specific
 8 individual cancer types. So I assume
 9 that that means that they were included
 10 for all cancers.
 11 Q. That's an assumption that
 12 you're making of the study?
 13 A. I think it's a pretty valid
 14 assumption.
 15 Q. Let's go down to exposure.
 16 MR. VAUGHN: The next
 17 paragraph, Tyler.
 18 BY MR. VAUGHN:
 19 Q. It notes the NDMA content of
 20 valsartan tablets seemed to correlate
 21 with the dose strength of the tablet.
 22 If that's inaccurate, is
 23 that going to impact the results of the
 24 study?

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1 A. I have no idea.
 2 Q. Why do you have no idea?
 3 A. Because I don't know if it's
 4 true or not. And I don't know how it
 5 would impact the study.
 6 Q. Well, is the study not
 7 trying to look at if higher levels of
 8 valsartan can cause cancer?
 9 MR. BALL: Object to form.
 10 THE WITNESS: It was looking
 11 at a variety of questions. That
 12 was just one of them.
 13 BY MR. VAUGHN:
 14 Q. Did they group people on
 15 exposure based on the milligram of the
 16 valsartan pill?
 17 A. You'd have to show me that
 18 so I can recall that. I don't recall off
 19 the top of my head.
 20 Q. You don't recall how they
 21 did this study?
 22 MR. BALL: Object to form.
 23 THE WITNESS: Not -- not
 24 off -- not off the top of my head,

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1 no.
 2 BY MR. VAUGHN:
 3 Q. If they did classify people
 4 for exposure based in part off of the
 5 milligram of the pill, and in reality
 6 some of the low milligram pills actually
 7 have more NDMA than the high milligram
 8 pills, would that impact the results of
 9 this study?
 10 MR. BALL: Object to form.
 11 THE WITNESS: I'd have to --
 12 I'd have to see how they're
 13 classified. I don't think it
 14 would impact the study though
 15 because there is no relationship
 16 between NDMA and cancer. I would
 17 say it would I still find no
 18 relationship.
 19 BY MR. VAUGHN:
 20 Q. Don't you base your opinion
 21 that there's no association between NDMA
 22 and cancer in large part on this study?
 23 MR. BALL: Objection to
 24 form.

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1 THE WITNESS: Not in large
2 part. The totality -- the
3 totality of the evidence.
4 BY MR. VAUGHN:
5 Q. How many valsartan studies
6 did you cite in your report?
7 A. Two.
8 Q. Two. And this is one of the
9 two, right?
10 A. Right.
11 Q. And the validity of the
12 results doesn't really matter how much
13 NDMA is in the pills because you're
14 already certain that NDMA is not
15 carcinogenic to humans, right?
16 MR. BALL: Objection to
17 form.
18 THE WITNESS: That's not
19 what I -- that's not what I said.
20 I think they analyzed it a
21 number of different ways.
22 BY MR. VAUGHN:
23 Q. How?
24 A. They looked at any valsartan

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1 use, valsartan use by different levels.
2 MR. VAUGHN: Tyler, can we
3 go to Page 5.
4 BY MR. VAUGHN:
5 Q. Doctor, do you know how many
6 people were included in this study that
7 got cancer?
8 A. I think -- I think it says
9 in the results section somewhere.
10 Here it is, no, these are
11 for the different cancer types. I can't
12 recall that off the top of my head.
13 Q. If we added up all the
14 cancer types, would that give us the
15 answer?
16 A. It depends if someone had
17 more than one cancer.
18 Q. Do you know if they --
19 earlier didn't we disagree that if they
20 were diagnosed with two cancers, they
21 weren't included?
22 MR. BALL: Objection to
23 form.
24 THE WITNESS: It wasn't

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1 they -- it wasn't that they were
2 diagnosed with two cancers. But
3 it should say in the results how
4 many people had cancer if you are
5 interested in that.
6 BY MR. VAUGHN:
7 Q. If you could find it, I'd
8 appreciate it. If I add all of these up,
9 I come out to about 28,000. I don't know
10 if that sounds about right to you or not.
11 A. I didn't memorize that. I'm
12 sorry. Let me see if I can -- can I
13 control this or do I have to download the
14 document?
15 Q. You might have to download
16 it.
17 A. Okay. What number is this,
18 what exhibit number?
19 MR. VAUGHN: Tyler, do you
20 know what --
21 TRIAL TECH: 25.
22 THE WITNESS: I'm sorry? I
23 missed that.
24 MR. VAUGHN: 25.

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1 TRIAL TECH: 25.
2 THE WITNESS: 25?
3 MR. VAUGHN: Yes.
4 THE WITNESS: All right. It
5 looks like we have to look at
6 eTable 1. Do you have eTable 1?
7 I take it it's an online table.
8 BY MR. VAUGHN:
9 Q. Page 3 has a Table 1, but
10 it's not giving that information.
11 A. Yeah. No, it's eTable,
12 which I assume means electronic table,
13 which means it's online. So I don't know
14 if you guys have access to that.
15 Q. I don't.
16 A. Okay. Because that gives a
17 result for overall cancer. So you'd have
18 to look at that.
19 Q. And so is it your opinion
20 that adding all the different cancer
21 types will not give us the total number?
22 MR. BALL: Objection to
23 form.
24 THE WITNESS: I have no

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1 idea. I said I had no idea.
2 BY MR. VAUGHN:
3 Q. Okay.
4 MR. VAUGHN: Well, let's go
5 back to Page 5, Tyler, and look at
6 all those cancers again.
7 BY MR. VAUGHN:
8 Q. Okay. So for bladder
9 cancer, between non-exposed and exposed,
10 if we add those together it's about
11 2,500, right?
12 A. Correct.
13 Q. And then breast cancer, if
14 we add those two together, it's about
15 4500, right?
16 A. I'll take your word for it.
17 I believe you.
18 Q. All right. And then
19 colorectal, you add those two together it
20 gets pretty close to 5,000, right?
21 A. Yes.
22 Q. And kidney, those two
23 together, is close to 2,000?
24 A. Yes.

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1 Q. And lung cancer, if we add
2 those together it's close to 4,000?
3 A. Yes.
4 Q. Malignant melanoma, we add
5 those together it's about 2,000?
6 A. Yes, it -- yes, it is.
7 Q. And pancreatic cancer, we
8 add those together, it's about 1,500?
9 A. Yes.
10 Q. And prostate cancer, we add
11 those together, it's about 5,000 --
12 4,000, right?
13 A. Yep.
14 Q. And then uterine cancer, we
15 add those together and it's about 1,000,
16 right?
17 A. Yeah. About 1100, 1200.
18 Q. So if I represent to you
19 that if we add all of those numbers that
20 we just did, we come out to 27,000. Do
21 you have any reason to disagree with
22 that?
23 MR. BALL: Objection to
24 form.

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1 THE WITNESS: If we add it
2 up?
3 BY MR. VAUGHN:
4 Q. Yeah, if we add all the
5 numbers that we just did, it comes out to
6 27,000.
7 A. Okay. I'll take your word
8 for it.
9 MR. VAUGHN: Then, Tyler,
10 can we now go to the last page,
11 Page 14.
12 BY MR. VAUGHN:
13 Q. Doctor, do you see here on
14 that first arrow that goes to the right,
15 14,608 people were excluded because they
16 did not have a consistent cancer
17 diagnosis?
18 A. Okay.
19 Q. And out of the total cancer
20 cases, so if there was that 27,000 that
21 were included, and you add these 14,600,
22 would you agree that about one-third of
23 the people diagnosed with cancer were
24 excluded from the study?

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1 A. I don't --
2 MR. BALL: Objection to
3 form.
4 BY MR. VAUGHN:
5 Q. Okay. So earlier we said
6 there was 27,000, we agreed, in the study
7 that got cancer.
8 A. Mm-hmm.
9 Q. And is 14,600 approximately
10 50 percent of 27,000?
11 A. Yes.
12 Q. So would that mean that
13 approximately one in three people
14 diagnosed with cancer were excluded from
15 the study?
16 MR. BALL: Objection to
17 form.
18 THE WITNESS: I don't
19 know -- I don't know unless we
20 look at the eTable 1 to see how
21 many cancer patients there were.
22 BY MR. VAUGHN:
23 Q. If the number we came to
24 earlier, the 27,000, if that was the

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1 total number of people that got cancer
2 that were included in the study, would
3 you agree that one-third were excluded?
4 MR. BALL: Objection to
5 form.
6 THE WITNESS: If that was,
7 yes.
8 BY MR. VAUGHN:
9 Q. Thank you, Doctor.
10 A. You should only be concerned
11 about that if they were not similar to
12 the people who were included. There's
13 bias involved in that.
14 Q. Well, the study was on
15 people that just took valsartan, right?
16 Earlier you were saying that they looked
17 at everyone that took valsartan, then
18 they compared that to the general
19 population, right?
20 A. No, they didn't compare this
21 to the general population. They only
22 compared it among valsartan users.
23 Q. Okay.
24 MR. VAUGHN: Let's go back

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1 to his expert report, Tyler. And
2 Page 26. Let's go to 56 now. We
3 left off at 55 last.
4 BY MR. VAUGHN:
5 Q. So midway through this one
6 it notes that the median NDMA cases was
7 0.18 nanogram a day and .16 --
8 A. Point --
9 Q. Huh? Do you see that?
10 A. I'm sorry, I'm trying to
11 figure out what this is. This is the
12 case of stomach cancer in Spain? Okay.
13 Q. Is this -- do you know if
14 this is correct, .18 nanograms or is that
15 supposed to be micrograms?
16 A. Oh, we'd have to look at the
17 study to confirm.
18 Q. All right. .18 nanograms is
19 really small, right?
20 A. Yeah, it is. Yeah.
21 Q. And just with a .02
22 increase -- .02-nanogram increase a day
23 of NDMA, they saw an increased risk of
24 cancer, didn't they?

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1 MR. BALL: Objection to
2 form.
3 THE WITNESS: I'm not sure
4 what you're asking. I'm sorry,
5 I'm a little bit lost.
6 BY MR. VAUGHN:
7 Q. Okay. Well, I guess the
8 next sentence, "An increasing risk of
9 stomach cancer was seen with increasing
10 NDMA intake."
11 Do you see that?
12 A. Yes.
13 Q. And that P-trend, .007,
14 that's statistically significant, right?
15 A. Correct.
16 Q. And if we look at the
17 quartiles. Quartile 2 is associated with
18 an 86 percent increase of risk.
19 Quartile 3, 79 percent increase of risk,
20 and then Quartile 4, 109 percent
21 increased risk, right?
22 A. Right.
23 Q. And then the difference on
24 the median intake, it looks like was

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1 just, what, .02 nanograms is what it was
2 saying?
3 A. Well, this is -- this is the
4 median across all four quartiles, right?
5 Q. You tell me.
6 A. You can't do what you did --
7 you can't do what you're doing.
8 Q. What am I doing?
9 A. You're looking across all
10 four quartiles.
11 Q. Is Quartile 4 the quartile
12 that got the most NDMA?
13 A. I believe that's how they
14 cut it up, yes.
15 Q. Is Quartile 4 the group that
16 had the highest increased risk of cancer?
17 A. Yes.
18 Q. Do you see later on where it
19 notes, "High NDMA intake paired with low
20 vitamin C intake increased the risk of
21 stomach cancer"?
22 A. Yes.
23 Q. And the high intake of
24 vitamin C appeared to mitigate the effect

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1 of high NDMA intake.
 2 Do you see that as well?
 3 A. I do.
 4 Q. Were you aware of that
 5 before working on your report?
 6 MR. BALL: Objection to
 7 form.
 8 THE WITNESS: That just this
 9 one study -- this one study showed
 10 a relationship?
 11 BY MR. VAUGHN:
 12 Q. I'm sorry. Were you aware
 13 that vitamin C could mitigate the
 14 carcinogenicity of low levels of NDMA?
 15 A. Well, this is just one
 16 study. You can't take the results of one
 17 study and say it's causality. It's the
 18 totality of the evidence.
 19 Q. Do you -- do you not think
 20 that vitamin C mitigates the
 21 carcinogenicity of NDMA?
 22 MR. BALL: Objection to
 23 form.
 24 THE WITNESS: I'd say we

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1 need more studies to show any type
 2 of causality. Absolutely.
 3 Confidence intervals are
 4 small. The risk odds ratios are
 5 small. They're not high. Only
 6 done in one population. You
 7 really need more information.
 8 BY MR. VAUGHN:
 9 Q. Do you know a person by the
 10 last name Wikoff, W-I-K-O-F-F?
 11 A. Yes.
 12 Q. How do you know them?
 13 A. She's at ToxStrategies.
 14 She's a toxicologist.
 15 Q. What about C. Thompson, do
 16 you know him?
 17 A. No.
 18 Q. And then Chappell, I think
 19 we talked about Chappell before, right?
 20 C-H-A-P-P-E-L-L?
 21 A. Yeah. I believe she's at
 22 ToxStrategies, yeah.
 23 Q. And then what about Doecker,
 24 D-O-E-P-K-E-R? Do you know that person?

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1 A. No, I don't know that name.
 2 Q. Okay. The ones that you do
 3 know, do you have any criticisms of them?
 4 MR. BALL: Objection to
 5 form.
 6 THE WITNESS: No.
 7 MR. VAUGHN: Tyler, can we
 8 pull up 2018 benefit risk
 9 analysis.
 10 (Document marked for
 11 identification as Exhibit
 12 Fryzek-26.)
 13 MR. VAUGHN: Can we go to
 14 Page 2.
 15 MR. BALL: I think you put
 16 this up before. Could you let me
 17 know what exhibit it was?
 18 MR. VAUGHN: This is the
 19 first time we've done this one.
 20 MR. BALL: Okay. Sorry.
 21 MR. VAUGHN: No, you're
 22 fine. It's confusing.
 23 BY MR. VAUGHN:
 24 Q. And, Doctor, does this

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1 identify that all of the authors of this
 2 study work at ToxStrategies?
 3 A. Yes.
 4 Q. And that's where you
 5 currently work, correct?
 6 A. I work at EpidStrategies,
 7 which is a division of ToxStrategies.
 8 Q. Thank you, Doctor.
 9 MR. VAUGHN: Tyler, can we
 10 go to Page 26. Maybe I'm wrong.
 11 26 at the bottom of it at least.
 12 Next page.
 13 BY MR. VAUGHN:
 14 Q. All right, Doctor. Can you
 15 read the first three sentences out loud
 16 for us?
 17 A. "The recent evaluation by
 18 EFSA" -- I don't know who EFSA is --
 19 "provides context regarding quantitative
 20 estimates related to formation of
 21 endogenous n-nitroso compounds in foods
 22 that contain nitrates as an additive."
 23 Q. I'm sorry, I have you on the
 24 wrong spot. I apologize for

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1 interrupting.
2 MR. VAUGHN: Can we pull
3 back out real quick, Tyler.
4 The top one, I'm sorry.
5 Yeah. I'll try it again.
6 BY MR. VAUGHN:
7 Q. Can you read the first three
8 sentences now for me?
9 A. "Significant complexities
10 are inherent" -- "are inherent to
11 quantitative evaluation of the potential
12 for formation of nitroso compounds. It
13 is recognized that there are processes
14 and agents that can reduce formation of
15 nitrosamines, for example, vegetables
16 containing vitamin C and other compounds
17 that inhibit nitrosation, causing reduced
18 formation of n-nitroso compounds, ATSDR
19 2017."
20 Q. And then can you skip down,
21 I guess, to the next -- skip one sentence
22 and start reading where it says "and
23 further complicating," and read through
24 the rest of the paragraph for us.

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1 A. "And further complicating
2 the evaluation of these compounds in the
3 context of nitrate exposures is
4 observation that although n-nitroso
5 compounds may have a role in cancer
6 etiology, consumption of fruits and
7 vegetables, sources of vitamins and
8 polyphenols, which can act as nitrosation
9 inhibitors, can produce protective
10 effects against various malignancies."
11 Q. Do you disagree with your
12 colleagues that n-nitroso compounds may
13 have a role in cancer etiology?
14 MR. BALL: Object to form to
15 form.
16 THE WITNESS: I'm sorry.
17 Can you ask again?
18 BY MR. VAUGHN:
19 Q. Do you disagree with your
20 colleagues that n-nitroso compounds may
21 have a role in cancer etiology?
22 MR. BALL: Objection.
23 THE WITNESS: I don't know
24 if this is -- I don't know if this

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1 is humans or animals we're talking
2 about here.
3 MR. VAUGHN: Can you go to
4 Page 4, Tyler. Or Page 5 of the
5 PDF, I think. Page 5.
6 There we go.
7 BY MR. VAUGHN:
8 Q. You see here that first
9 sentence, it's talking about, "Recent
10 data suggests that it may be an important
11 and beneficial constituent in the human
12 diet."
13 So we're talking about human
14 diet here, correct?
15 A. I'm sorry. Where are you
16 reading?
17 Q. Very first paragraph or
18 sentence.
19 A. Okay. That's what that
20 sentence refers to.
21 Q. Do you not think that the
22 entire study is talking about human diet?
23 MR. BALL: Object to form.
24 THE WITNESS: I don't know.

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1 I haven't had the opportunity to
2 read it.
3 BY MR. VAUGHN:
4 Q. Did you not consult with
5 your colleagues when you were forming
6 your opinions in this report?
7 MR. BALL: Objection to
8 form.
9 THE WITNESS: So these are
10 my opinions, not my colleagues'
11 opinions?
12 BY MR. VAUGHN:
13 Q. No, these are your
14 colleagues' opinions.
15 Did you consult with any of
16 the authors of this manuscript when you
17 were developing your opinions in this
18 case?
19 A. Why would I? They're
20 toxicologists. They don't know anything
21 about epidemiology.
22 Q. But I knew that you worked
23 on a panel --
24 A. They're different

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1 disciplines. They're different
2 disciplines.
3 Q. Well, but I notice on your
4 billing you had a lot of different people
5 actually doing the review and writing
6 your report. And some of them just said
7 professionals and stuff. None of these
8 people would have been involved at all
9 with helping you draft your report or
10 doing research, correct?
11 A. Correct.
12 Q. And then back on Page 27, do
13 you disagree with them that n-nitroso
14 compounds may have a role in cancer
15 etiology?
16 MR. BALL: Objection to
17 form.
18 MR. VAUGHN: Sorry, go back
19 one page, Tyler. It's confusing
20 on PDF versus the other page.
21 BY MR. VAUGHN:
22 Q. Yeah, here at the bottom
23 where they say, "N-nitroso compounds may
24 have a role in cancer etiology."

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1 Do you disagree with that?
2 MR. BALL: Objection to
3 form.
4 THE WITNESS: I don't know
5 if they're talking-- I don't know
6 if they are talking about humans
7 or animals.
8 BY MR. VAUGHN:
9 Q. If they are talking about
10 humans, do you disagree with your
11 colleagues?
12 MR. BALL: Objection to
13 form.
14 THE WITNESS: Again,
15 epidemiology data doesn't show
16 that.
17 BY MR. VAUGHN:
18 Q. So you're saying yes, you do
19 disagree with your colleagues?
20 MR. BALL: Objection to
21 form.
22 THE WITNESS: I'm saying
23 that I don't -- I don't know what
24 this study is about. I don't know

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1 what they did. All I know is what
2 I reviewed. And my review shows
3 the totality of the evidence,
4 there's no relationship between
5 NDMA and cancer or any specific
6 cancer type.
7 MR. VAUGHN: We can go back
8 to his expert report now, Tyler,
9 and Page 26 again.
10 BY MR. VAUGHN:
11 Q. Number 57, I think that's
12 the one we are on. About midway through
13 it notes that "The mean daily NDMA intake
14 for this population was
15 .18 micrograms" -- and that would be
16 180 nanograms, correct, Doctor?
17 A. I believe so, yes.
18 Q. And this one is in Italy,
19 correct?
20 A. Yes.
21 Q. And then the next sentence
22 says, "Using the fully adjusted model,
23 there was an increased risk of stomach
24 cancer at the highest intake of NDMA,"

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1 when they are taking over 191 nanograms.
2 Do you see that?
3 A. I do.
4 Q. And do you have any idea if
5 the NDMA levels in valsartan were over
6 198 nanograms?
7 MR. BALL: Objection to
8 form.
9 BY MR. VAUGHN:
10 Q. You don't know if they were
11 hundreds of times higher or even
12 thousands of times higher than that?
13 MR. BALL: Objection to
14 form.
15 THE WITNESS: I don't know.
16 It doesn't matter for the
17 epidemiology review.
18 With all the epidemiology
19 studies and overall there's not a
20 risk with cancer.
21 BY MR. VAUGHN:
22 Q. Then if you go a little bit
23 farther do you see where it says,
24 "However, a dose-response trend was

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1 observed, P less than .01."
 2 So is that saying there's a
 3 statistically significant dose-response
 4 with NDMA and stomach cancer in this
 5 study?
 6 A. In men, but not in women.
 7 Q. Previously we looked at a
 8 study, who had higher levels of NDMA
 9 intake in their diet, was it men or
 10 women?
 11 MR. BALL: Objection to
 12 form.
 13 THE WITNESS: I don't know.
 14 But you can't take one study from
 15 a different population and
 16 different country and apply it to
 17 a study in a different country
 18 with a different population.
 19 BY MR. VAUGHN:
 20 Q. We've looked at quite a few
 21 different countries now, haven't we?
 22 MR. BALL: Objection to
 23 form.
 24 THE WITNESS: Yes.

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1 Absolutely.
 2 MR. VAUGHN: Let's go to the
 3 next page, Tyler.
 4 BY MR. VAUGHN:
 5 Q. All right. Number 58.
 6 All right, Now we are in
 7 France. And if we go down about
 8 two-thirds of the way.
 9 "Median daily intake of NDMA
 10 was .25 micrograms."
 11 So here the median is
 12 250 nanograms, isn't it?
 13 A. Yes.
 14 Q. Which is getting higher,
 15 right?
 16 A. Getting higher than --
 17 MR. BALL: Objection to
 18 form.
 19 BY MR. VAUGHN:
 20 Q. Higher than the previous
 21 ones we looked at?
 22 A. I don't recall.
 23 Q. For which --
 24 A. Some of them were -- some

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1 were means and some were median, so
 2 they're different -- they're different
 3 measures. Median isn't the same as a
 4 mean.
 5 Q. But do you agree that
 6 250 nanograms was higher than the other
 7 ones we were looking at, that were like
 8 50 nanograms and 70 nanograms?
 9 MR. BALL: Objection to
 10 form.
 11 THE WITNESS: If they -- I
 12 can't recall, I think they were
 13 means. These are different
 14 measures. You can't compare them.
 15 BY MR. VAUGHN:
 16 Q. So but for the median daily
 17 NDMA intake at 250 nanograms, there was a
 18 statistically significant higher
 19 increased of cancer than in the controls,
 20 correct?
 21 MR. BALL: Objection to
 22 form.
 23 THE WITNESS: They didn't do
 24 it -- they didn't do analysis by

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1 median. So I'm confused by your
 2 answer.
 3 BY MR. VAUGHN:
 4 Q. I'm reading what it says on
 5 your report, on median daily NDMA intake
 6 was 250 nanograms. When they compared
 7 250 nanograms to 230 nanograms there was
 8 a statistically significant higher -- oh,
 9 is that just saying that the -- is that
 10 just saying that the NDMA intake was
 11 higher, not the risk of cancer?
 12 A. Correct.
 13 Q. Okay.
 14 A. It doesn't say it -- it just
 15 says difference.
 16 Q. Okay. Can you read the next
 17 sentence aloud for us?
 18 A. "There was a sevenfold risk
 19 of stomach cancer with the highest NDMA
 20 intake, and a nonsignificant increased
 21 risk in the middle tertile."
 22 Q. And what does the next
 23 sentence say?
 24 A. "A dose-response trend was

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1 observed when NDMA was analyzed as a
2 continuous variable. Results were
3 adjusted for age, sex, occupation, and
4 total caloric intake."
5 Q. So what is your explanation
6 for why this one showed a sevenfold
7 increase in stomach cancer?
8 MR. BALL: Objection to
9 form.
10 THE WITNESS: You have --
11 you have to look at how the study
12 was conducted. You have to look
13 at all the confounders.
14 So H. pylori is considered
15 for stomach cancer here, which is
16 a major confounder. And different
17 population. You have to look at
18 all those things.
19 BY MR. VAUGHN:
20 Q. Do you have any evidence at
21 all that one group had higher rates of
22 H. pylori than the other?
23 MR. BALL: Objection to
24 form.

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1 THE WITNESS: I have no
2 evidence -- I have no evidence
3 that they didn't. I'm saying it's
4 something that you need to look
5 at, you need to look at it. You
6 can't just ignore it.
7 BY MR. VAUGHN:
8 Q. Do you look at that in every
9 study that you do?
10 MR. BALL: Objection to
11 form.
12 THE WITNESS: I don't do a
13 lot of studies -- I don't do a lot
14 of studies of stomach cancer.
15 BY MR. VAUGHN:
16 Q. So H. pylori would be one
17 confounder, correct? Can you name any
18 other ones besides H. pylori for this
19 one?
20 MR. BALL: Objection to
21 form.
22 THE WITNESS: Yeah, we have
23 to go to page -- I list all the
24 confounders. Let me find them for

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1 you.
2 BY MR. VAUGHN:
3 Q. We are talking about a
4 700 percent increase. Do you think a
5 confounder can explain a 700 percent
6 increase?
7 And that's just average. If
8 you look at this, it goes from 1.85 to
9 26.46. That is a 2,600 percent increase
10 in cancer, is it not?
11 MR. BALL: Object to form.
12 THE WITNESS: You are
13 misinterpreting what that's
14 showing. What that's showing is
15 there's just not a lot of people
16 at that highest intake level.
17 Because the confidence interval is
18 so wide, 1.85 to 26.46. It's just
19 unstable.
20 BY MR. VAUGHN:
21 Q. And the lowest part of that
22 confidence interval is still showing
23 85 percent increased risk of cancer,
24 isn't it?

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1 A. But it's quite a wide
2 confidence interval.
3 So I'm trying to find my --
4 the list of confounders for stomach
5 cancer. Do you want me to still find
6 that or?
7 Q. You know, I was going to get
8 to that in a little bit if we want to
9 just wait.
10 A. Okay.
11 Q. So I think we went through
12 five stomach NDMA studies, all of them so
13 far found an increased risk of stomach
14 cancer with increasing risk of NDMA.
15 Let's go --
16 A. Again, we just --
17 MR. BALL: Is that a
18 question? Is that a question or a
19 statement?
20 MR. VAUGHN: I wasn't even
21 done yet. I was going to say
22 let's go to Number 59.
23 BY MR. VAUGHN:
24 Q. Again midway through this

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1 one, NDMA intake was found to be
2 associated with an increased risk of
3 stomach cancer, odds ratio 1.15, P-trend
4 .001.
5 So is this now the sixth
6 study in a row that we've went through
7 that shows --
8 A. Yeah --
9 Q. -- an association with NDMA
10 and cancer?
11 A. You can't just cherry-pick
12 studies like this. You have to look at
13 all of the totality together.
14 Q. Doctor, what do you mean --
15 what do you mean cherry-pick? I'm going
16 through them in order of your report.
17 These are the first six ones that you
18 listed under stomach cancer. How am I
19 cherry-picking?
20 A. Let's look at the graph and
21 see what they all look like together.
22 Q. Why the graph? Why can't we
23 go through --
24 A. Because --

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1 Q. -- what you actually said
2 about these?
3 A. I did the graph as well. I
4 mean --
5 Q. Okay. And your attorney can
6 ask you questions. He can go through
7 your graph with you if you want. But how
8 am I cherry-picking when I'm going
9 through them one by one in the order you
10 put them in your report?
11 A. I am not sure that you're
12 going through them one by one. I haven't
13 been paying attention to that. And I
14 don't know why you don't want to look at
15 my graph. It's a representation of all
16 these studies.
17 Q. I've been calling out the
18 number each time. 55, okay, let's go to
19 the next one, 56, 57, 58. 59 is where
20 we're at.
21 A. Okay. You must be in the
22 section that's just on stomach cancer
23 too, right?
24 Q. All right. Let's move on

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1 then from stomach cancer. Let's go to --
2 let's go to Page 29 where it starts going
3 into upper aerodigestive cancers. Number
4 63, the first one in that section in your
5 expert report.
6 All right. If we go down
7 about halfway again.
8 "Cancer of the oral cavity
9 was increased with NDMA intake, but only
10 statistically significant at the highest
11 intake levels."
12 Do you see that, Doctor?
13 A. I do. Yes.
14 MR. VAUGHN: You can go to
15 the next page.
16 BY MR. VAUGHN:
17 Q. So you only have two listed
18 under upper aerodigestive cancers. Okay.
19 So the one we just went over. And we're
20 going to go over to Number 64, which is
21 the other one. And towards the bottom of
22 that one is --
23 A. But you're --
24 Q. -- it says, "NDMA was found

Page 341

1 to be associated with ESSC," which is
2 esophageal squamous cell carcinoma. And
3 it ranges from 2.12, se even the lowest
4 end of the confidence -- confidence
5 interval was above two. And it goes all
6 the way to 5.07 with a P trend of .0001,
7 correct?
8 A. Yeah, so you're only looking
9 at the poor study designs here. You're
10 ignoring the cohort studies, which we
11 reviewed at first. We looked at those.
12 You're ignoring the actual studies of
13 valsartan.
14 MR. VAUGHN: Tyler, can we
15 go back to Page 24 of his report.
16 BY MR. VAUGHN:
17 Q. Do you see at the top there,
18 Doctor, you're talking specifically about
19 case-control studies. You said that --
20 A. Right.
21 Q. -- assessed as a whole have
22 not found strong evidence that NDMA or
23 NDEA are associated with cancer.
24 You only listed two

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1 case-control studies for upper airway.
2 And they both show a statistically
3 significant result.
4 How do you get to this
5 opinion when you only have two studies
6 that both show it?
7 A. I have to look at my graph.
8 My graph was pretty clear about it.
9 Q. Your graph is going to be
10 able to explain more than the paragraphs
11 that you wrote about the studies?
12 A. Yeah, because you'll be able
13 to see all the evidence in totality.
14 Q. But you would agree with me
15 the only two studies that you cited for
16 upper aerodigestive cancers on
17 case-control studies, they both showed a
18 statistically significant increased risk?
19 MR. BALL: Objection to
20 form.
21 THE WITNESS: The strongest
22 of these designs are cohort
23 studies, and they don't show a
24 risk.

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1 BY MR. VAUGHN:
2 Q. Okay. But how can you say
3 that the case-control studies do not show
4 evidence?
5 A. Because they don't. The
6 lower confidence intervals are way below
7 two.
8 Q. Okay. Let's go back to Page
9 30. Remember the low confidence interval
10 is 2.12. That's above two, correct?
11 A. Slightly above two, yes.
12 Q. It's above two, right?
13 A. It is, yes.
14 Q. So where are you coming out
15 saying that the case-control studies
16 don't show an increased risk of cancer?
17 You only have two studies cited here.
18 Your excuse a second ago was the lower
19 end of the confidence interval was under
20 two. It's above two. So what's your
21 reason now?
22 MR. BALL: Objection to
23 form.
24 THE WITNESS: Of this one

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1 study or all the studies combined?
2 BY MR. VAUGHN:
3 Q. The case-control studies.
4 A. When you look at all the
5 studies combined -- that's why we graph
6 them, so you can see them all combined.
7 You don't just pull them out one by one.
8 Q. You only list two studies
9 under upper aerodigestive cancers. They
10 both show a statistically significant
11 increased risk. How are you saying that
12 case-control studies don't show any
13 evidence that NDMA or NDEA are associated
14 with cancer? You only list two
15 case-control studies and they both show
16 an increased risk, do they not?
17 A. Okay. Okay.
18 MR. BALL: Objection to
19 form.
20 THE WITNESS: And you have
21 to -- you have to look at all of
22 the methodologies of the studies.
23 And case-control studies of the
24 diet are really hard to do.

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1 BY MR. VAUGHN:
2 Q. I don't see anywhere in your
3 report where you are explaining why these
4 two studies don't support evidence that
5 NDMA is associated with cancer. I mean,
6 the authors found that it was, right?
7 MR. BALL: Objection to
8 form.
9 THE WITNESS: I don't know.
10 I can't recall what the authors
11 said about the finding.
12 BY MR. VAUGHN:
13 Q. This part where it says,
14 NDMA was found to be associated with
15 ESSC, esophageal squamous cell carcinoma,
16 and then they give an odds ratio 3.28, a
17 95 percent confidence interval from 2.12
18 to 5.07 and a P-trend of .0001.
19 Was that your analysis or
20 was that the authors' analysis?
21 A. Oh, it's the authors'
22 analysis, absolutely.
23 Q. Let's move on to colorectal
24 cancer. Number 65. We go about halfway

Page 346

1 down. "Intake of NDMA was found to be
2 associated with risk of colorectal cancer
3 at the highest level of intake."
4 And then you skip two
5 sentences.
6 Do you notice again where
7 they say, "However a dose-response trend
8 was observed, P-trend .005," correct?
9 A. Correct.
10 Q. We'll keep going. There was
11 also, "The highest levels of NDMA intake
12 were associated with cancer of the
13 rectum." And it lists it as
14 statistically significant, correct?
15 A. Correct.
16 Q. And if we look at a little
17 higher, Q5 median was 2.29 micrograms a
18 day, correct?
19 A. In this population, yes.
20 Q. You don't have any idea if
21 some of the valsartan contained more than
22 two micrograms of NDMA, do you?
23 A. I don't, no.
24 Q. Doctor, this is the only

Page 347

1 case-control study that you listed for
2 colorectal cancer. But again, remember
3 earlier you said there was no evidence in
4 the case-control studies of increased
5 risk of cancer, right?
6 MR. BALL: Objection to
7 form.
8 BY MR. VAUGHN:
9 Q. Do you think this study
10 supports the fact this there's not an
11 increased risk of cancer with NDMA?
12 A. I thought the lower
13 confidence interval is below two, way
14 below two in both of these studies.
15 THE COURT REPORTER: Can you
16 raise your voice, please, Doctor?
17 THE WITNESS: I said the
18 lower confidence interval is below
19 two, way below two in both of
20 these studies.
21 BY MR. VAUGHN:
22 Q. So -- there's only one
23 study, I think, isn't there?
24 A. I'm sorry, in both of these

Page 348

1 findings, the two findings there. The
2 rectum cancer, colorectal cancer.
3 Q. But -- lowest end of that
4 confidence interval still showed an
5 increased risk of cancer, right?
6 A. A borderline. Borderline.
7 Q. Borderline increased risk of
8 cancer?
9 A. Yeah.
10 Q. Okay.
11 MR. VAUGHN: Let's go to the
12 next page.
13 BY MR. VAUGHN:
14 Q. So again, you have one study
15 cited for pancreas cancer.
16 A. Mm-hmm.
17 Q. And those, "Plant sources of
18 NDMA were associated with statistically
19 significant increased risk at high levels
20 of intake compared to low levels."
21 P-trend .001, correct?
22 A. Correct. Which you have to
23 be mindful of how they are doing the
24 study. I mean, you're just looking at --

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1 again, you're just looking at the
2 findings here. I mean they -- so they
3 did the study and they only looked at
4 diet in the past year. They didn't look
5 at any changes in the diet. They didn't
6 look at lifetime diet. A lot of
7 questions you have in this type of study.
8 And I explain that at the very beginning
9 about the problems with frequency
10 questionnaires in these type of diet
11 studies.
12 Q. Do you know if exposure to a
13 mutagenic carcinogen like NDMA can cause
14 cancer in one year?
15 MR. BALL: Objection to
16 form.
17 THE WITNESS: I don't know
18 that.
19 BY MR. VAUGHN:
20 Q. And pancreatic cancer is
21 what this one is looking at, right?
22 A. It is.
23 Q. And you discuss earlier
24 about how people die so quickly from

Page 350

1 pancreatic cancer, right?

2 A. Yeah. And now they are

3 thinking about what they are -- different

4 exposures to different things. We try to

5 assess all those things.

6 Q. So you think some people

7 might be saying they eat more plant-based

8 food that's high in NDMA because they

9 have -- they got pancreatic cancer?

10 MR. BALL: Objection to

11 form.

12 THE WITNESS: Pancreatic --

13 in my pancreatic cancer study, we

14 were looking at the risk of DDT

15 associated with pancreatic cancer.

16 We put in some fake

17 pesticides to see if they would be

18 more likely to pick the pesticides

19 that are fake than controls.

20 That's the way we tried to control

21 for it.

22 But they didn't do anything

23 like that in these studies.

24 THE COURT REPORTER: Doctor,

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1 if you could really just try to

2 throw your voice for me, please.

3 Thank you.

4 THE WITNESS: Yep, yeah.

5 BY MR. VAUGHN:

6 Q. The study you did on if DDT

7 increases the risk of pancreatic cancer,

8 do you recall the results of that study?

9 A. Yeah. I think that some

10 forms of DDT showed pancreatic cancer.

11 Q. Really.

12 Are there any other

13 chemicals that you've studied that you've

14 come to the conclusion that they are

15 associated with an increased risk of

16 cancer besides DDT?

17 A. It wasn't DDT. It was some

18 forms of DDT. And I can't recall the

19 other ones.

20 Q. All right. Go to --

21 A. I just remember that one

22 because it was my first study.

23 Q. You remember your first

24 study, but not your first deposition?

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1 MR. BALL: Objection to

2 form.

3 THE WITNESS: It's a little

4 more -- little more meaningful.

5 BY MR. VAUGHN:

6 Q. All right, let's go to

7 confounding factors. And if you need a

8 bathroom break or anything at any time

9 let me know.

10 What is a confounding

11 factor?

12 A. It is a third factor that is

13 associated with both the exposure and the

14 disease. If you don't control for it you

15 may see spurious associations. Like a

16 nuisance factor.

17 Q. And something that can be a

18 symptom of the outcome would not be a

19 confounder, correct?

20 A. A symptom of --

21 MR. BALL: Object to form.

22 BY MR. VAUGHN:

23 Q. Correct.

24 A. No, it wouldn't be a

Page 353

1 confounder.

2 Q. All right. For bladder

3 cancer you list certain workplace

4 exposures.

5 A. I think all of these come

6 from the American Cancer Society. If you

7 just go on their web page you'll see

8 these.

9 Q. Okay. And you rely on them

10 for -- so you're relying on the

11 American -- I'm sorry, who was it again,

12 American Cancer Society?

13 A. American -- oh yeah, the

14 regulatory organization.

15 Q. Okay. You note smoking is a

16 risk factor. Do cigarettes contain NDMA

17 or NDEA?

18 A. I believe so.

19 MR. VAUGHN: Go to the next

20 page, Tyler.

21 BY MR. VAUGHN:

22 Q. It notes occupation

23 industries up there at the top, and one

24 of them is rubber.

Page 354

1 The rubber industry. Are
 2 they -- are those workers exposed to high
 3 levels of NDMA?
 4 A. It's really not clear from
 5 the studies. They are exposed to so many
 6 different things, it's hard to
 7 understand.
 8 Q. Are one of the things they
 9 are exposed to NDMA?
 10 A. I believe some of the
 11 studies have shown that they are. But
 12 it's hard to tease out just the NDMA
 13 exposure by itself.
 14 Q. What's this P word diabetes
 15 medication, do you see that? Pio? In
 16 the second sentence?
 17 A. Where are you reading?
 18 Q. Right there.
 19 A. Oh. It's a -- it's a new
 20 type of diabetic medication. I can't
 21 remember what it's called.
 22 Q. Is it Actos maybe?
 23 A. I can't recall. You have to
 24 look at the American Cancer Society web

Page 355

1 page.
 2 Q. Are you aware that that drug
 3 is a mutagenic carcinogen?
 4 MR. BALL: Object to form.
 5 THE WITNESS: I have no
 6 idea. I have no idea.
 7 BY MR. VAUGHN:
 8 Q. Do you know that -- do you
 9 know Dr. Botorff, one of the defense
 10 experts in this case, a pharmacist?
 11 A. I don't know that name.
 12 Q. You don't know him? He told
 13 me that he kept giving this drug to his
 14 patients even after it got a black box
 15 warning for cancer.
 16 A. Okay.
 17 MR. BALL: Objection to
 18 form.
 19 BY MR. VAUGHN:
 20 Q. You list chemotherapy and
 21 radiation as a risk factor. Why is that?
 22 A. It's what's on the American
 23 Cancer Society web page.
 24 Q. Do you agree that that's a

Page 356

1 risk factor for bladder cancer?
 2 A. I agree with what the
 3 American Cancer Society lists on their
 4 web page. Absolutely, yeah.
 5 Q. Do you have -- you have no
 6 basis for why chemotherapy or radiation
 7 might increase the risk someone gets
 8 cancer?
 9 A. I assume they reviewed the
 10 evidence of that.
 11 Q. But you don't know what the
 12 mechanism of action is?
 13 A. Oh no, I don't know.
 14 Q. Do immunosuppressives
 15 increase the risk of cancer?
 16 A. I'm sorry?
 17 Q. Does something that's an
 18 immunosuppressant, does that increase the
 19 risk of someone getting cancer?
 20 A. I don't know.
 21 MR. VAUGHN: Let's move to
 22 69, blood cancer.
 23 BY MR. VAUGHN:
 24 Q. So you mentioned radiation,

Page 357

1 certain chemo again, or having a weakened
 2 immune system from taking immune
 3 suppression medication.
 4 Would you agree that immune
 5 suppression can increase the risk of
 6 getting cancer?
 7 MR. BALL: Objection to
 8 form.
 9 BY MR. VAUGHN:
 10 Q. Was that a yes you do agree?
 11 MR. BALL: Objection to
 12 form.
 13 THE WITNESS: Some cancers,
 14 not -- not all cancers.
 15 BY MR. VAUGHN:
 16 Q. Which cancers?
 17 A. This section is on blood
 18 cancer, right?
 19 Q. It is.
 20 Do you know if NDMA is an
 21 immunosuppressant?
 22 A. That, I don't know. But I
 23 know NDMA is not a medication. You're
 24 talking about immunosuppression

Page 358

1 medications.

2 Q. It lists breast implants as

3 a risk. Do you agree with that?

4 A. Where? Oh. Yeah, there's a

5 rare form of non-Hodgkin's lymphoma that

6 is associated. That's really -- that's

7 kind of a new finding.

8 Q. And do you agree with that

9 finding?

10 A. I haven't evaluated the

11 evidence. I assume it's true, because

12 the American Cancer Society reports on

13 it.

14 Q. Have you ever done any

15 research on breast implants and the

16 complications they can cause?

17 A. I've done a lot, yes.

18 Q. And were you receiving

19 funding from the corporation when you

20 were doing those studies?

21 A. I don't know. Again, that

22 was when I was at IEI. So I don't know

23 whose funds those were.

24 Q. Who is Dow Corning

Page 359

1 Corporation?

2 A. I'm sorry?

3 Q. Do you know what Dow Corning

4 Corporation is?

5 A. It's an industry,

6 absolutely.

7 Q. What type of industry?

8 A. I believe they used to

9 make -- they used to make breast

10 implants. But I don't think they do

11 anymore.

12 Q. Okay. And when they were

13 funding your research, do you recall if

14 you found that breast implants, that they

15 were associated with anything?

16 MR. BALL: Objection to

17 form.

18 THE WITNESS: Yes. Yes.

19 BY MR. VAUGHN:

20 Q. What were -- what were

21 breast implants associated with in the

22 studies you did?

23 A. Suicide.

24 Q. So was your conclusion of

Page 360

1 those studies that breast implants don't

2 increase the risk of any disease, but

3 women are just more likely to be crazy?

4 MR. BALL: Objection to

5 form.

6 THE WITNESS: I don't think

7 that's a statement from any of my

8 papers. You have to show me where

9 I said that.

10 BY MR. VAUGHN:

11 Q. Did you say that they have a

12 higher rate of mental health issues?

13 MR. BALL: Objection to

14 form.

15 THE WITNESS: I don't -- I

16 don't recall. These are studies

17 that I did over 20 years ago. So

18 I don't recall.

19 BY MR. VAUGHN:

20 Q. If your studies contradict

21 with what the American Cancer Society

22 says now, do you not retract those

23 studies?

24 MR. BALL: Objection to

Page 361

1 form.

2 THE WITNESS: So I think

3 you're talking about this rare

4 non-Hodgkin's lymphoma finding

5 that said -- I think people agree

6 that that is a finding on breast

7 implants. But I don't know enough

8 about it because I didn't study

9 it.

10 MR. VAUGHN: Let's go back

11 to his expert report. Page 32.

12 We're still on the expert report.

13 Sorry. Number 70.

14 I guess we can skip 70.

15 It's on breast cancer, and we're

16 not alleging breast cancer.

17 BY MR. VAUGHN:

18 Q. Colorectal cancer, 71. You

19 note that in the U.S. African Americans

20 have the highest incidence and mortality

21 rates of colorectal cancer of all racial

22 groups.

23 Why did you include that?

24 A. It's an important factor.

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1 Q. Why is it an important
 2 factor?
 3 A. Because it's a risk if
 4 you're African American. Absolutely.
 5 Q. Why is it a risk if you're
 6 an African American?
 7 MR. BALL: Objection to
 8 form.
 9 THE WITNESS: Because they
 10 show -- I'm a little bit confused
 11 by your question. But I assume
 12 it's because the studies of the
 13 American Cancer Society, based on
 14 the findings, show an increased
 15 risk for African Americans.
 16 BY MR. VAUGHN:
 17 Q. Have you ever studied
 18 colorectal cancer and the risk of African
 19 Americans getting it?
 20 A. I have not, no.
 21 MR. VAUGHN: Tyler, can we
 22 pull up 2010, Use of Electronic
 23 Medical Records.
 24 (Document marked for

Page 363

1 identification as Exhibit
 2 Fryzek-27.)
 3 BY MR. VAUGHN:
 4 Q. You were an author on this
 5 paper, correct, Jon -- or Dr. Fryzek?
 6 A. I was, yes.
 7 Q. And this was in 2010. Were
 8 you working at Exponent at this time?
 9 A. I was at Amgen.
 10 Q. Were you ever working at
 11 Exponent the same time that you were
 12 working at Amgen?
 13 A. Oh, no. You can't do that.
 14 Q. And these first three people
 15 that are all of Exponent, do you know
 16 them?
 17 A. Fionna is still at Exponent.
 18 I think Libby has gone back to a faculty
 19 position. Gena, I don't know what's
 20 happened to her.
 21 Q. Okay. Did you say --
 22 A. This was a long time ago.
 23 Q. Was Fionna the one that you
 24 said is still at Exponent?

Page 364

1 A. I believe she is, yeah.
 2 Q. Do you still work with her?
 3 A. No.
 4 MR. VAUGHN: Can we go to
 5 Page 9, Tyler. Bottom right
 6 paragraph.
 7 BY MR. VAUGHN:
 8 Q. Doctor, is this discussing
 9 different rates of cancer with different
 10 ethnicity groups?
 11 A. It is.
 12 Q. Do you where it says, "Rates
 13 of cancer incidence, mortality, and
 14 survival may differ by age, race,
 15 ethnicity, socioeconomic status, economic
 16 (sic) attainment level, and geographic
 17 location, and it is thought that access
 18 to healthcare screening and treatment
 19 resources and the quality of treatment
 20 given may underlie a large proportion of
 21 these differences."
 22 Do you see that?
 23 A. I do.
 24 Q. If we go a little bit

Page 365

1 further down, it says, "Researchers found
 2 that black patients were significantly
 3 less likely than white patients to
 4 receive therapy for their cancer."
 5 Do you think that's why
 6 there's a higher mortality rate of
 7 colorectal cancer in United States with
 8 African Americans?
 9 MR. BALL: Objection to
 10 form.
 11 THE WITNESS: I have no
 12 idea.
 13 BY MR. VAUGHN:
 14 Q. You have no idea if access
 15 to medical care might impact their death
 16 rate?
 17 MR. BALL: Objection to
 18 form.
 19 THE WITNESS: No. You have
 20 to understand how this study is
 21 similar to, you know, the data
 22 that the American Cancer Society
 23 is looking at, how representative
 24 it is, those types of things.

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1 Are they looking at the same
2 age group? I don't know.
3 BY MR. VAUGHN:
4 Q. Do you agree that catching
5 the cancer early increases someone's
6 survival rate?
7 MR. BALL: Objection to
8 form.
9 THE WITNESS: That, I don't
10 know. I haven't done any studies
11 on that.
12 BY MR. VAUGHN:
13 Q. Do you think it's easier to
14 treat Stage I cancer or Stage IV cancer?
15 MR. BALL: Objection to
16 form.
17 THE WITNESS: Oh, Stage I.
18 Stage I.
19 BY MR. VAUGHN:
20 Q. So if someone caught their
21 cancer at Stage I before it progressed,
22 they'd have a higher chance of surviving,
23 right?
24 MR. BALL: Objection to

Page 367

1 form.
2 THE WITNESS: I don't know.
3 It depends on the cancer, et
4 cetera, what the comorbidities
5 are, things like that.
6 BY MR. VAUGHN:
7 Q. Number 72. Esophageal
8 cancer. And if we go on the next page,
9 on 33, where it's talking about it.
10 MR. BALL: Hey, Brett, are
11 you nearing a good place for a
12 stop? We've gone about an hour
13 and fifteen.
14 MR. VAUGHN: We can stop
15 right now if you want to.
16 MR. BALL: Okay. Why don't
17 we take a little break. Ten
18 minutes?
19 MR. VAUGHN: Yeah.
20 Appreciate it.
21 THE VIDEOGRAPHER: Off the
22 record, 3:16.
23 (Short break.)
24 THE VIDEOGRAPHER: We are

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1 back on the record at 3:26.
2 BY MR. VAUGHN:
3 Q. Doctor, earlier you stated
4 that it would have been improper for you
5 to work at Exponent while you were
6 working at Amgen.
7 Does the same apply to when
8 you were working at MedImmune?
9 A. Yes.
10 Q. And as your report states,
11 you were working at one of those two
12 companies from 2006 to 2012, correct?
13 A. If my report states it,
14 that's correct.
15 MR. VAUGHN: Tyler, can we
16 go back to Page 33 of his report.
17 Let's just go ahead and skip down
18 to lung cancer, 76.
19 BY MR. VAUGHN:
20 Q. You note probable risk
21 factors.
22 Probable risk factors,
23 that's something that is not confirmed to
24 be a carcinogen?

Page 369

1 A. Correct.
2 Q. So something like NDMA would
3 fall under a probable risk factor as
4 well?
5 MR. BALL: Objection to
6 form.
7 THE WITNESS: I believe the
8 probable risk factors from the
9 American Cancer Society for lung.
10 BY MR. VAUGHN:
11 Q. And do you see one,
12 beryllium, B-E-R-Y-L-L-I-U-M. How do you
13 say that?
14 A. Beryllium.
15 Q. Do you agree with the
16 American Cancer Society that that is a
17 risk factor for lung cancer?
18 A. I haven't evaluated all the
19 evidence of that. I don't know. I don't
20 know off the top of my head.
21 Q. Have you ever evaluated that
22 evidence?
23 A. I have looked at beryllium
24 in terms of cancer, but I can't remember

Page 370

1 the findings. Been about ten years, I
2 think.
3 Q. Okay.
4 MR. VAUGHN: Tyler, can we
5 pull up 2011, occupational
6 exposure to beryllium.
7 TRIAL TECH: One second. I
8 might not have added this as well.
9 I know I saw this as one of the
10 exhibits that was sent.
11 MR. VAUGHN: 2012, sorry.
12 TRIAL TECH: Oh, that's why.
13 MR. VAUGHN: It got put in
14 there wrong. It should say '11.
15 (Document marked for
16 identification as Exhibit
17 Fryzek-28.)
18 BY MR. VAUGHN:
19 Q. Okay. So the top left-hand
20 corner, this was actually published in
21 2012. But at the bottom you can see that
22 it was received in July of 2011. And you
23 were one of the authors on this article,
24 correct, Dr. Fryzek?

Page 371

1 A. The second author, yes.
2 Q. And there's a little
3 Number 2 after your name, right?
4 A. I'm sorry, I can't see it.
5 It's kind of hard -- yes.
6 Q. And what does that 2
7 indicate?
8 A. At the time that this was
9 written I was at Exponent in Alexandria,
10 Virginia.
11 Q. And at what time was this
12 wrote?
13 A. I can't recall.
14 Q. If we go to the very bottom
15 of this page --
16 A. I think -- it was while I
17 was at Exponent.
18 Q. So 2011 you were at
19 Exponent?
20 A. When this was written I was
21 at Exponent. I have no idea.
22 Q. So it wouldn't have been
23 after 2011, right?
24 A. Pardon me?

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1 Q. It would not have been after
2 2011, right?
3 A. It looks like -- it looks
4 like not, correct.
5 Q. And you don't think you
6 wrote this before 2006, do you?
7 A. I don't think so, no.
8 Q. Do you recall testifying
9 that between 2006 and 2012, you were
10 working at Amgen and MedImmune, and that
11 it would have been improper for you to be
12 working at Exponent at the same time?
13 A. Well, maybe I was off on my
14 dates of the pharmaceutical companies. I
15 can't recall.
16 Q. Are you going to look back
17 into that to see when your actual
18 employment dates were?
19 A. I think it's on my LinkedIn
20 profile too.
21 Q. Is your LinkedIn profile
22 more accurate than your expert report?
23 MR. BALL: Objection to
24 form.

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1 THE WITNESS: It should
2 be -- it should be the same.
3 MR. VAUGHN: Let's go to the
4 abstract, that first page still.
5 If you can blow up the abstract
6 words.
7 BY MR. VAUGHN:
8 Q. Can you read the last
9 sentence for us, the overall?
10 A. "Overall, the available
11 evidence does not support a conclusion
12 that a causal association has been
13 established between occupational exposure
14 to beryllium and the risk of cancer."
15 Q. Do you think that should
16 really should be a risk factor that's
17 controlled for in the lung cancer studies
18 if you don't even think it's associated
19 with lung cancer?
20 A. Yeah, because you don't
21 control for risk factors, you --
22 MR. BALL: Objection.
23 THE WITNESS: -- you
24 control -- when you control for

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1 items in a relationship, you
2 control for those that are known
3 to be risk factors and those that
4 are potentially risk factors.
5 BY MR. VAUGHN:
6 Q. Would the potential risk
7 factors have a smaller confounding effect
8 than known risk factors?
9 A. I have no idea.
10 Q. If it doesn't actually
11 increase the risk of cancer, is it going
12 to be a confounder?
13 A. If what doesn't increase the
14 risk of cancer?
15 Q. If anything. Like let's say
16 beryllium in this example. If it does
17 not increase the risk of cancer at all,
18 is it going to be a confounder?
19 A. I think there's a little bit
20 of confusion of what a confounder is. So
21 a confounder you're not looking at the
22 totality of the evidence, you're looking
23 at confounding within a study.
24 Q. When you defined confounder

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1 earlier, you said it must affect both
2 exposure and outcome. And so if it's not
3 actually increasing the risk of cancer,
4 how is it affecting the outcome?
5 A. Again, you have to look at
6 the study specifically. If it increases
7 the risk of cancer within that study,
8 then it is a confounder. And it's
9 associated with exposure. So it's a
10 study-specific idea.
11 Q. What do you base that off
12 of?
13 A. Base what off of?
14 Q. What you just said, that
15 confounders are study specific.
16 A. Oh. General epidemiology.
17 Q. So if one study is looking
18 at lung cancer, and the other study is
19 looking at lung cancer, is -- beryllium
20 can get confounder in one and not the
21 other?
22 A. Correct. Ethnicity can be.
23 Age can be.
24 The way to control by

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1 confounding is done by age is having a
2 certain age group. Then you are
3 confounding by age.
4 Q. If beryllium though doesn't
5 actually increase the risk of lung
6 cancer, how is it impacting the results
7 of studies that don't control for
8 beryllium exposure?
9 A. Again, confounding is a very
10 study-specific thing. You have to look
11 within each study.
12 Q. Do you have any reason to
13 believe that any of the studies that you
14 reviewed that beryllium was a confounder?
15 A. I can't recall.
16 MR. VAUGHN: Can you go to
17 Page 10, Tyler, of this study.
18 Keep going. One more page.
19 BY MR. VAUGHN:
20 Q. Who funded this study,
21 Doctor?
22 A. Looks like it was Materion
23 Brush.
24 Q. Do you know why they funded

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1 this study?
2 A. I don't.
3 Q. Do you know if they had
4 anything to do with beryllium exposure
5 from any of their products?
6 A. I think they manufactured
7 beryllium, but I'm not sure. I wasn't
8 involved in getting this grant.
9 Q. Who was involved in getting
10 the grant?
11 A. Dr. Mandel.
12 Q. And he also worked for
13 Exponent, correct?
14 A. At that time, did.
15 Q. Do you still work with
16 Dr. Mandel?
17 A. No.
18 Q. Do you know where he works
19 now?
20 A. I haven't seen for more
21 than -- I believe he's retired. But I
22 haven't seen him for more than ten years.
23 MR. VAUGHN: Go back to the
24 expert report again, Tyler. Same

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1 spot we were at. Page 33.
2 BY MR. VAUGHN:
3 Q. You see where they list
4 chromium compounds, or where you listed
5 chromium compounds as a risk factor for
6 lung cancer as well?
7 A. Yeah. Again, it's under
8 American Cancer Society.
9 Q. And do you agree with the
10 American Cancer Society saying that
11 chromium is a risk factor for lung
12 cancer?
13 A. I think they listed it. I
14 don't know how they make the decision. I
15 would include it as a risk factor --
16 confounder. Absolutely.
17 Q. I'm sorry. I'm reading the
18 transcript. I'm having a hard time
19 hearing you.
20 A. I'm sorry. I'll try to
21 speak up. I'll hold my microphone up a
22 little.
23 Q. You're fine. I gotcha. You
24 said you would include it as a risk

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1 factor. Okay. But --
2 A. I said as a confounder.
3 Q. As a confounder?
4 A. Yeah.
5 Q. Do you not think that
6 chromium is a risk factor for cancer?
7 A. That wasn't the purpose of
8 my review here, my research.
9 Q. I understand but I'm asking
10 you specifically. Do you not think that
11 chromium is a risk factor for cancer?
12 MR. BALL: Objection to
13 form.
14 THE WITNESS: I don't know.
15 BY MR. VAUGHN:
16 Q. You don't know if chromium
17 is a risk factor for cancer?
18 A. I have to review the
19 literature. I haven't reviewed the
20 literature on chromium.
21 Q. Have you published
22 literature on chromium?
23 A. I believe I have. I can't
24 recall. I can't recall for sure.

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1 MR. VAUGHN: Tyler, can we
2 pull up 2001, Cancer Mortality
3 Chromium Exposure.
4 THE WITNESS: Oh, yeah. I
5 thought I had.
6 (Document marked for
7 identification as Exhibit
8 Fryzek-29.)
9 THE WITNESS: Sorry. It's
10 hard to remember 30 years of
11 research.
12 MR. VAUGHN: So let's start
13 with the right-hand side, Tyler.
14 First big, long paragraph.
15 BY MR. VAUGHN:
16 Q. Do you see where it says,
17 "Although the evidence for
18 carcinogenicity of trivalent chromium is
19 lacking, hexavalent chromium is
20 classified as a human carcinogen."
21 Do you see that?
22 A. Yes.
23 Q. Your study, if we look at
24 the abstract part on the left, found

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1 there was no evidence cancer hazard
2 though with residents living near these
3 California gas compressors, correct?
4 A. Correct.
5 MR. VAUGHN: Can we go to
6 the next page, Tyler.
7 Top left. Yeah those two
8 paragraphs.
9 BY MR. VAUGHN:
10 Q. Why is this talking about
11 Erin Brockovich? Is that the movie Erin
12 Brockovich?
13 A. Yes.
14 Q. Is that what the people in
15 that movie were exposed to is chromium?
16 A. Supposedly, yes. Allegedly.
17 Q. And PG&E, is that who was
18 being sued for the chromium exposure in
19 Erin Brockovich?
20 A. Oh, that, I don't know.
21 Q. Okay. Outside the movie, is
22 PG&E who was being sued for chromium
23 exposure?
24 A. Again, I don't know.

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1 MR. BALL: Objection.
2 BY MR. VAUGHN:
3 Q. Do you see where it says,
4 "Which was settled in 1996." And our --
5 the report says, "The litigation against
6 PG&E, which was settled." So PG&E was
7 being sued for chromium exposure, right?
8 A. I assume so.
9 Q. And the next paragraph says,
10 "Given these concerns, we were asked by
11 PG&E to conduct a study of mortality
12 among residents." Right?
13 A. Yes.
14 Q. And the study they paid you
15 to do, you didn't find any association
16 with chromium and cancer, correct?
17 A. Again, this wasn't a study
18 that they paid me to do. I was paid by
19 International Epidemiology Institute with
20 a regular salary.
21 Q. And who paid IEI?
22 A. Oh, I don't know. I wasn't
23 involved with that.
24 Q. I mean it says, "Given these

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1 concerns, we were asked by PG&E to
2 conduct a study." Do you think they
3 asked IEI, and IEI is just, like, "Yeah,
4 we'll do it for free"?
5 MR. BALL: Objection to
6 form.
7 THE WITNESS: I get --
8 again, I was not involved in
9 getting grants or invoicing. I
10 was just a researcher.
11 BY MR. VAUGHN:
12 Q. You were the lead author on
13 this, weren't you?
14 A. Yeah, absolutely.
15 Q. You actually wrote this
16 paragraph, right?
17 A. I don't recall who wrote it.
18 Q. Didn't you testify earlier
19 that the lead author is the one that's
20 actually writing it?
21 A. It's usually the lead
22 author. Yes.
23 MR. VAUGHN: Can we go to
24 Page 3, Tyler.

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1 BY MR. VAUGHN:
2 Q. I'm on the right-hand side,
3 the first paragraph that starts
4 "occupational studies."
5 Doctor, can you read that
6 first sentence aloud for us?
7 A. "Occupational studies have
8 been a mainstay of medical research to
9 identify and quantify the risks of cancer
10 and other diseases associated with
11 chemical exposures."
12 Q. Do you still agree with that
13 statement?
14 A. I guess it depends on what
15 occupational studies you're talking
16 about, how well they are done, things
17 like that --
18 Q. But in --
19 A. In general, yes.
20 Q. In general. Thank you.
21 A. Mm-hmm.
22 MR. VAUGHN: Can we go to
23 Page 5, Tyler. And bottom left,
24 two paragraphs. Yeah.

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1 BY MR. VAUGHN:
2 Q. So you guys weren't actually
3 able to determine the exposure levels to
4 the hexavalent chromium, were you?
5 A. No, we weren't.
6 Q. But that was okay for this
7 study, correct?
8 A. It depends on what the
9 objectives of the study were. So it was
10 okay for this study.
11 Q. Would occupational studies
12 that are able to actually measure the
13 doses be more accurate?
14 MR. BALL: Objection.
15 THE WITNESS: This isn't an
16 occupational study. This is a
17 community study. This is done on
18 the community members.
19 BY MR. VAUGHN:
20 Q. So with the community as
21 well, would that study be even more valid
22 if you did know the levels?
23 MR. BALL: Objection to
24 form.

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1 THE WITNESS: I'm sorry.
2 Can I have the question again?
3 BY MR. VAUGHN:
4 Q. Scratch it. It probably
5 wasn't a very good one.
6 The next paragraph you note
7 that you guys examined cancer mortality,
8 not cancer incidence?
9 A. Correct.
10 Q. What are the downsides to
11 doing a mortality study versus an
12 incidence study?
13 MR. BALL: Objection to
14 form.
15 THE WITNESS: Oh, cancer
16 mortality, the downside is
17 cancer -- if you're diagnosed and
18 you live a long time, you know,
19 it's a misrepresentation of cancer
20 incidence.
21 Usually they're pretty good.
22 BY MR. VAUGHN:
23 Q. Okay. I think that's what
24 you're actually -- your study says --

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1 MR. VAUGHN: If we go to the
2 next column, Tyler, at the top.
3 BY MR. VAUGHN:
4 Q. It says, "Even for cancers
5 with relatively good survival, although
6 the statistical power of mortality
7 studies will be reduced for cancers with
8 higher survival rates."
9 Is that what you were just
10 describing?
11 A. Yeah.
12 Q. Well, can you give me some
13 examples of types of cancers with high
14 survival rates?
15 A. Typically the blood cancers,
16 leukemia, lymphoma.
17 Q. What about, like, prostate
18 cancer?
19 A. Prostate cancer, yes.
20 Q. And so --
21 A. Yeah.
22 Q. So studies that are only
23 looking at cancer mortality instead of
24 cancer incidence, they might not actually

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1 catch the statistical -- statistically
2 significant increased risk of cancer for
3 things like blood cancers or prostate
4 cancers, correct?
5 MR. BALL: Objection to
6 form.
7 THE COURT REPORTER: I
8 didn't hear an answer if you said
9 one.
10 THE WITNESS: I can't
11 remember the question. Can you
12 read the question back?
13 MR. VAUGHN: I believe you
14 said correct.
15 BY MR. VAUGHN:
16 Q. The question was: So
17 studies that are only looking at cancer
18 mortality instead of cancer incidence,
19 they might not actually catch the
20 statistically significant increased risk
21 of cancer for things like blood cancer or
22 prostate cancers, correct?
23 A. Yeah. And I said correct.
24 Yeah.

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1 Q. Thank you.
2 Is your company still
3 researching chromium?
4 A. You mean my company now?
5 Q. Yeah.
6 A. Oh, not to my knowledge. I
7 don't know. I don't have any
8 epidemiological studies on chromium.
9 Q. Deborah Proctor. You know
10 her, correct?
11 A. Yes.
12 Q. Who is she again?
13 A. She is one of the co-owners.
14 Q. Do you know Bhat, B-H-A-T?
15 A. Who?
16 Q. Person with the last name of
17 Bhat, B-H-A-T?
18 A. I don't know.
19 Q. Mina Suh, that's who was
20 helping you with your report, right?
21 A. Correct. She is an
22 epidemiologist.
23 Q. Okay.
24 MR. VAUGHN: Can we pull up

<p>Page 390</p> <p>1 2021, inhalation cancer risk 2 assessment, Tyler. 3 (Document marked for 4 identification as Exhibit 5 Fryzek-30.) 6 MR. VAUGHN: And if we can 7 zoom in on the authors. 8 BY MR. VAUGHN: 9 Q. And can you give me the 10 authors and the stuff right below it that 11 says where they work? 12 And so all of these authors 13 at the time at least worked either in 14 your division at ToxStrat or at ToxStrat, 15 right? 16 A. Yeah. Heidi and Xiaohui are 17 statisticians. 18 Q. Heidi and who? 19 A. Xiaohui. 20 Q. Okay. Did any of these 21 people besides Mina Suh help you with 22 your report? 23 A. No. 24 Q. And Mina Suh was the main</p> <p>Page 391</p> <p>1 person that helped you, correct? 2 A. No. 3 Q. Who was the main person that 4 helped you? 5 A. Sue Pastula. 6 Q. Can you say that one more 7 time? 8 A. Sue Pastula. 9 MR. VAUGHN: And can we go 10 to Page 13, Tyler. 11 BY MR. VAUGHN: 12 Q. And on the right-hand side 13 where it says funding. So is your 14 company still receiving funding as of 15 2021 from the electrical -- Electric 16 Power Institute? 17 A. I have no idea. Again, this 18 is ToxStrategies which is a different 19 group than EpidStrategies. 20 EpidStrategies doesn't have any money 21 from Electrical Power Research Institute. 22 Q. But Mina Suh, is she at 23 EpidStrategies or ToxStrategies? 24 A. She was at ToxStrategies. I</p>	<p>Page 392</p> <p>1 assume, based on this article, that she 2 started this study when she was at 3 ToxStrategies and then she moved over to 4 EpidStrategies when we came because we 5 were all epidemiologists. 6 Q. What about Heidi Reichert, 7 it says that she was at EpidStrategies at 8 this time? 9 A. Right. Heidi and Xiaohui 10 are statisticians. 11 Q. And so people within your 12 company were being employed to do 13 chromium studies for the Electric Power 14 Research Institute? 15 A. It looks like they were 16 employed to do some research analysis. 17 I'm not sure what they were doing. 18 MR. VAUGHN: Can we go to 19 Page 13 again, Tyler. 20 Can we get the paragraph 21 right above funding. 22 And if we -- midway through. 23 BY MR. VAUGHN: 24 Q. "Until such data are</p> <p>Page 393</p> <p>1 developed, it is important to consider 2 and clearly communicate that assuming the 3 existence of an increased risk of cancer 4 at environmentally relevant exposures is 5 a policy decision not clearly supported 6 by the scientific evidence." 7 Do you agree with that 8 statement? 9 MR. BALL: Objection to 10 form. 11 THE WITNESS: I don't agree 12 or disagree. This is one area -- 13 this is an area of study, and it's 14 also toxicology so I can't really 15 respond. 16 BY MR. VAUGHN: 17 Q. If they are saying that the 18 environmental exposure of chromium is not 19 going to increase your risk of cancer, 20 then why are you saying that it's a 21 potential risk factor that could have 22 confounded the results in the studies in 23 your expert report? 24 MR. BALL: Objection to</p>
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1 form.
2 THE WITNESS: I'm not -- I'm
3 not saying that. That's from the
4 American Cancer Society.
5 BY MR. VAUGHN:
6 Q. So your employees, or your
7 colleagues, I guess, that published this
8 study are in disagreement with the
9 American Cancer Society?
10 MR. BALL: Objection to
11 form.
12 THE WITNESS: I have no
13 idea.
14 As I said, this is the first
15 time I've seen this study. And
16 it's about toxicology, not
17 epidemiology, so I don't know.
18 MR. VAUGHN: Tyler, can we
19 go to 2006 -- one sec. Yep.
20 Did I upload the 2006
21 corporate corruption document,
22 Tyler?
23 TRIAL TECH: I have two,
24 2006 documents. One is a cohort

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1 study. The other one is a
2 Parkinson's one that we used
3 earlier today.
4 MR. VAUGHN: That's what I
5 thought. I'll have this one sent
6 over. We can skip that one.
7 All right. Could we go back
8 to his expert report. Page 33.
9 BY MR. VAUGHN:
10 Q. Are you on your phone,
11 Doctor?
12 A. Pardon?
13 Q. Are you on your phone?
14 A. Yeah. I had to cancel my --
15 I had to cancel my gym class tonight.
16 It's getting too late.
17 MR. VAUGHN: Oh, that's why
18 I couldn't find it, Tyler. I
19 apologize. Can we do
20 E-G-I-L-M-A-N, dash 2006? I
21 forgot to change the file name
22 when I uploaded it.
23 (Document marked for
24 identification as Exhibit

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1 Fryzek-31.)
2 TRIAL TECH: I'm just
3 looking for it now. Give me one
4 second.
5 BY MR. VAUGHN:
6 Q. Doctor, have you ever heard
7 of someone named Dennis Paustenbach,
8 P-A-U-S-T-E-N-B-A-C-H?
9 A. Yes.
10 Q. Who is that?
11 A. I believe a toxicologist. I
12 think he is a toxicologist.
13 Q. Have you ever worked with
14 him?
15 A. No.
16 TRIAL TECH: Brett, I'm not
17 seeing this file either. I don't
18 have it downloaded and I don't
19 have it in the DropBox folder.
20 MR. VAUGHN: Okay.
21 E-G-I-L-M-A-N. If you don't see
22 it, that's fine. I just want to
23 double-check.
24 TRIAL TECH: It starts with

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1 A-G-I-L?
2 MR. VAUGHN: E. E.
3 TRIAL TECH: Oh, okay. I
4 see it now.
5 MR. VAUGHN: Cool. Sorry
6 about that.
7 TRIAL TECH: That's okay.
8 This the one you're looking for?
9 MR. VAUGHN: Yeah.
10 MR. BALL: Okay.
11 MR. VAUGHN: Can we go to
12 Page 2.
13 BY MR. VAUGHN:
14 Q. So, "Convening the panel,"
15 that paragraph under there.
16 It talks about a blue ribbon
17 panel. Do you know what that is, Doctor?
18 A. I don't.
19 Q. Just noting this was in
20 2001. That was -- that study we looked
21 at a second ago, that was a 2001 study,
22 correct?
23 A. I don't recall.
24 Q. Do you know a Brent Finley?

<p>Page 398</p> <p>1 A. No.</p> <p>2 MR. VAUGHN: Can we go to</p> <p>3 the bottom, where it says,</p> <p>4 "Balanced representation of</p> <p>5 science and scientists"?</p> <p>6 BY MR. VAUGHN:</p> <p>7 Q. It says within a week of</p> <p>8 this panel being made, Dennis</p> <p>9 Paustenbach, former principal at</p> <p>10 ChemRisk, was appointed to the panel.</p> <p>11 And Brent Finley of Exponent says, "So it</p> <p>12 looks like we've got one of our own on</p> <p>13 the panel." Up on the next paragraph.</p> <p>14 Do you see where it says</p> <p>15 that?</p> <p>16 A. Yep.</p> <p>17 Q. Do you know if ChemRisk was</p> <p>18 a division of Exponent?</p> <p>19 A. I have no idea.</p> <p>20 Q. Do you know what he means by</p> <p>21 one of our own on the panel?</p> <p>22 A. No. This is, what, 2001? I</p> <p>23 wasn't at Exponent until, what, 2012, you</p> <p>24 said, 2011?</p> <p>Page 399</p> <p>1 Q. Yeah, but you were</p> <p>2 publishing literature in 2001 on chromium</p> <p>3 as well, correct?</p> <p>4 A. Okay. I was, yeah.</p> <p>5 Q. Was Deborah Proctor, is she</p> <p>6 the one that works at ToxStrat?</p> <p>7 A. Yeah.</p> <p>8 MR. VAUGHN: Can we go to</p> <p>9 Page 6, Tyler, of the PDF, the</p> <p>10 third paragraph. It starts, "On</p> <p>11 July 25, 2001."</p> <p>12 BY MR. VAUGHN:</p> <p>13 Q. Do you see where it says</p> <p>14 that she gave testimony as a</p> <p>15 representative of the Alliance For</p> <p>16 Responsible Water Policy without</p> <p>17 acknowledging that the Alliance was</p> <p>18 funded by PG&E or that she had consulted</p> <p>19 for them in the past?</p> <p>20 A. Okay.</p> <p>21 Q. Are you aware of that?</p> <p>22 A. No.</p> <p>23 MR. BALL: Objection to</p> <p>24 form.</p>	<p>Page 400</p> <p>1 THE WITNESS: I'm not even</p> <p>2 aware it's true. I'm not even</p> <p>3 aware it's true.</p> <p>4 I mean, you're quoting from</p> <p>5 this journal that I know that is a</p> <p>6 plaintiff journal. And this is</p> <p>7 pointing that out. And I don't</p> <p>8 know what the references are, so.</p> <p>9 BY MR. VAUGHN:</p> <p>10 Q. International Journal of</p> <p>11 Occupational Environmental Health is a</p> <p>12 plaintiffs journal?</p> <p>13 A. Oh, absolutely.</p> <p>14 Q. Do you publish in that</p> <p>15 journal?</p> <p>16 A. No.</p> <p>17 Q. Is it just the Journal of</p> <p>18 Occupational Health that you -- is that</p> <p>19 the one that you publish in?</p> <p>20 A. I'm not sure what you're</p> <p>21 asking. I'm sorry.</p> <p>22 Q. Give me one second. I'll</p> <p>23 take a look.</p> <p>24 I'll work it out later.</p> <p>Page 401</p> <p>1 A. Who is the author of this</p> <p>2 paper that you're showing me?</p> <p>3 MR. BALL: Jon, you can</p> <p>4 download it if you want to</p> <p>5 download it and take it to the top</p> <p>6 to see who the author is.</p> <p>7 THE WITNESS: It's in the</p> <p>8 exhibits?</p> <p>9 MR. BALL: It should be in</p> <p>10 the exhibits, yeah. It's Exhibit</p> <p>11 Number -- hold on.</p> <p>12 THE WITNESS: Number 1?</p> <p>13 MR. BALL: No, no, it's</p> <p>14 Exhibit Number --</p> <p>15 TRIAL TECH: 31.</p> <p>16 MR. BALL: 31.</p> <p>17 BY MR. VAUGHN:</p> <p>18 Q. Where it says --</p> <p>19 A. This is authored by David</p> <p>20 Egilman. I'm wondering if he lists all</p> <p>21 of his plaintiff testimony. It doesn't</p> <p>22 look like he does. So it's a little bit</p> <p>23 of a conflict of interest.</p> <p>24 Q. Okay. Well, let's see who</p>
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1 actually said this statement has a
2 conflict of interest.
3 So she gave testimony as a
4 representative of the Alliance For
5 Responsible Water Policy without
6 acknowledging either that the Alliance
7 was funded by PG&E or that she had
8 consulted for PG&E in the past. And
9 there's a little 48 after it, right?
10 A. Okay.
11 MR. VAUGHN: If we go two
12 pages later, Tyler, and blow up
13 48.
14 BY MR. VAUGHN:
15 Q. And, Doctor, can you read
16 off what that citation is?
17 A. "Senate hearing of the
18 Senate Health & Human Services Committee,
19 Possible Interference in the Scientific
20 Review of Chromium VI Toxicity,
21 February 28, 2003."
22 I have no idea what that
23 means.
24 Q. Do you think it's like the

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1 United States Senate?
2 MR. BALL: Objection to
3 form.
4 THE WITNESS: It doesn't say
5 that.
6 BY MR. VAUGHN:
7 Q. Health & Human Services
8 Committee? Are you aware if that's a
9 part of the U.S. Senate?
10 MR. BALL: Objection to
11 form.
12 THE WITNESS: I don't know
13 if it's U.S. or California or
14 another state. I have no idea.
15 BY MR. VAUGHN:
16 Q. Do you think whatever
17 Health & Human Services Committee works
18 for the plaintiffs?
19 A. I have no idea.
20 Q. Do you know if the
21 government is allowed to even work in
22 lawsuits?
23 MR. BALL: Objection to
24 form.

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1 THE WITNESS: I have no
2 idea. I don't work for the
3 government. It's too bad that
4 Egilman didn't disclose his
5 relationships with plaintiffs.
6 BY MR. VAUGHN:
7 Q. If it's true that Deborah
8 Proctor did not disclose all of this, is
9 that problematic?
10 MR. BALL: Objection to
11 form.
12 THE WITNESS: I have -- I
13 have absolutely no idea.
14 BY MR. VAUGHN:
15 Q. Is there any company policy
16 at ToxStrat to disclose all financial
17 interest when doing studies?
18 MR. BALL: Objection to
19 form.
20 THE WITNESS: I have no
21 idea.
22 BY MR. VAUGHN:
23 Q. You don't know if that's a
24 company policy?

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1 A. No.
2 MR. VAUGHN: If you can go
3 back to his expert report again
4 Tyler. 78, pharyngeal cancer.
5 BY MR. VAUGHN:
6 Q. And at the top, do you see
7 where it says, "Well-confirmed risk
8 factors for nasopharyngeal cancer," and
9 one of the things included is
10 salt-preserved fish?
11 A. Okay.
12 Q. Do you remember earlier we
13 went over that salt-preserved fish had
14 the highest levels of NDMA?
15 MR. BALL: Objection to
16 form.
17 THE WITNESS: I don't --
18 BY MR. VAUGHN:
19 Q. Sorry. I can't hear what
20 you said.
21 A. I don't recall. I don't
22 know what study you're looking at. I
23 don't know if all studies had shown that.
24 You can't just pull out one finding and

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1 say that represents the whole literature.
2 You have to look at the literature in
3 totality.
4 Q. Overall, is salt-preserved
5 fish one of the foods with the highest
6 level of NDMA?
7 MR. BALL: Objection.
8 THE WITNESS: I have no
9 idea.
10 BY MR. VAUGHN:
11 Q. Didn't look into that at all
12 in forming your opinions in this case?
13 MR. BALL: Objection to
14 form.
15 THE WITNESS: No.
16 BY MR. VAUGHN:
17 Q. Let's go on to 77 on
18 pancreatic cancer.
19 Do you see where you listed
20 diabetes and obesity as risk factors for
21 pancreatic cancer?
22 A. Yes, that's what it says.
23 Q. When it comes to the
24 confounders, if they are very similar, do

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1 you have to control for both of them?
2 A. Again, it's a study-specific
3 thing. So you have to look at the study
4 and how it's related to the exposure and
5 the disease.
6 Q. In your opinion, is diabetes
7 a risk factor for pancreatic cancer?
8 A. So I haven't studied that.
9 I don't know.
10 MR. VAUGHN: Tyler, can we
11 go to 2007, the association
12 between selected risk factors.
13 (Document marked for
14 identification as Exhibit
15 Fryzek-32.)
16 MR. VAUGHN: Blow up the
17 names in the bottom left.
18 BY MR. VAUGHN:
19 Q. So were you working at the
20 University of Michigan at this time in
21 2007?
22 A. Yes. This is -- actually
23 this is my dissertation, part of my
24 dissertation.

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1 Q. And what is a dissertation?
2 A. On pancreatic cancer.
3 Q. What's dissertation mean?
4 A. A dissertation for my Ph.D.
5 Q. And so you were not working
6 at IEI at this time, correct?
7 A. It looks like I wasn't. It
8 says I was at Amgen during this time.
9 Q. Okay.
10 A. But this is just data I
11 analyzed off my Ph.D. data that I had.
12 Q. And so the title of this
13 study notes Expression of p53 and K-ras
14 Codon 12 mutations. Do you know if Amgen
15 was developing drugs targeting those?
16 A. Not to my knowledge.
17 Q. To your -- you don't know if
18 Amgen at this time has drugs on the
19 market focused on K-ras?
20 MR. BALL: Objection to --
21 objection to form.
22 THE WITNESS: Not for
23 pancreatic cancer. Not for
24 pancreatic cancer.

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1 BY MR. VAUGHN:
2 Q. So in abstract, that first
3 paragraph you note that there are a few
4 risk factors for pancreatic cancer,
5 including cigarette smoking, BMI,
6 relative with pancreatic cancer, and
7 diabetes. A few less risk factors than
8 you listed in your expert report,
9 correct?
10 A. I'm sorry?
11 Q. You list -- you list more
12 risk factors in your expert report
13 though, correct?
14 A. From the American Cancer
15 Society, yes.
16 MR. VAUGHN: Let's go on the
17 right-hand side of this.
18 BY MR. VAUGHN:
19 Q. And so for your dissertation
20 paper you did in-person interviews to
21 ascertain information such as
22 demographics and lifestyle factors,
23 correct?
24 A. Correct.

<p>Page 410</p> <p>1 Q. And under results, the 2 smoking, was that statistically -- was 3 that associated with an increase? 4 A. Borderline. It was 0.9 to 5 4.3. 6 Q. And so even though it was 7 below one, it's still associated with an 8 increased risk, correct? 9 A. No. It's borderline 10 related. 11 MR. VAUGHN: Go to the next 12 page, Tyler. 13 BY MR. VAUGHN: 14 Q. That top paragraph notes p53 15 mutations. What is a p53 mutation? 16 A. It's a type of mutation on 17 the tumor. That's all I know about it. 18 Q. You're the head author, this 19 is your dissertation paper, right? 20 A. Right. Talking about 21 15 years ago. I haven't looked at it 22 since then, so... 23 MR. VAUGHN: All right. Can 24 we go further down, Tyler, the</p> <p>Page 411</p> <p>1 second paragraph under 2 introduction? 3 BY MR. VAUGHN: 4 Q. And you see where it says, 5 "It has been observed that both K-ras 6 oncogene and tumor suppressor gene p53 7 are often highly mutated in pancreatic 8 cancer." 9 I read that correctly? 10 A. Okay, yes. 11 Q. Do you agree with that 12 statement? 13 A. I agree that it's accurate, 14 what I wrote there. And it -- that 15 reference says that. 16 Q. Does that mean that most 17 people that get pancreatic cancer, they 18 have a mutation of one of their genes, 19 the p53 or the K-ras? 20 A. I don't think so. 21 MR. BALL: Objection to 22 form. 23 BY MR. VAUGHN: 24 Q. What does it mean?</p>	<p>Page 412</p> <p>1 A. So we were trying to look at 2 the prevalence or how often these 3 appeared in pancreatic cancer. 4 Q. It says -- 5 A. You'd have to look at my 6 results to see. 7 Q. But this sentence does say 8 "often highly mutated in pancreatic 9 cancer," correct? 10 A. It does say that, yes. 11 Q. Okay. And then just the 12 next sentence, "If these markers of 13 genetic damage are related to 14 environmental or lifestyle exposures, it 15 can be hypothesized that this variation 16 may be because of different exposures to 17 potential carcinogens," correct? 18 A. Correct. 19 Q. All right. 20 MR. VAUGHN: Go to the next 21 paragraph, Tyler. 22 BY MR. VAUGHN: 23 Q. And it notes the information 24 that you ascertained from them. Can you</p> <p>Page 413</p> <p>1 read that for me? 2 "Diagnosed workup and 3 ascertained information"? 4 A. I'm sorry, I'm not clear 5 where you're reading. 6 Q. You're fine. Second 7 sentence, we collected. 8 A. "We collected histological 9 material from pancreatic cancer patients 10 during their diagnostic workup and 11 ascertained information on a variety of 12 potential exposures related to pancreatic 13 cancer risk, including smoking habits, 14 body mass index, family history of 15 pancreatic cancer, obesity, and history 16 of diabetes." 17 Q. But did you not evaluate 18 what dietary exposures these people might 19 have had? 20 A. We didn't, not in this 21 study. 22 Q. And so you didn't assess 23 NDMA exposure at all when you were doing 24 your study, did you?</p>
--	--

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1 A. No. This was a case-control
2 study. And as I said, it's really hard
3 to estimate diet in case-control studies.
4 Q. But your theory was that it
5 might be a result of environmental
6 carcinogens, right?
7 MR. BALL: Objection to
8 form.
9 THE WITNESS: What might be
10 a result of environmental
11 carcinogens?
12 BY MR. VAUGHN:
13 Q. I'm sorry, I can't hear you.
14 A. What might be the result of
15 environmental carcinogens?
16 MR. VAUGHN: Can we go to
17 Page 6, Tyler. Top left.
18 BY MR. VAUGHN:
19 Q. Doctor, you see where it
20 says, "The p53 tumor suppressor gene is
21 found to be altered in almost all human
22 tumors, reflecting its critical role as a
23 tumor suppressor"?
24 A. Okay.

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1 Q. Would you agree that if a
2 compound can alter the p53 gene, that
3 it's going to increase the risk of
4 cancer?
5 MR. BALL: Objection to
6 form.
7 THE WITNESS: You know, I
8 just don't know. I don't know.
9 MR. VAUGHN: And can we go
10 to the last paragraph on this
11 side, the left-hand side.
12 BY MR. VAUGHN:
13 Q. And about midway through it
14 says however.
15 Doctor, can you read that
16 sentence aloud for us?
17 A. "However, one concern
18 regarding the association between
19 diabetes and pancreatic cancer is the
20 probability that diabetes may be a
21 consequence of pancreatic cancer rather
22 than a cause as a number of studies have
23 reported higher risk of increasing years
24 before diagnosis of pancreatic cancer."

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1 Q. And so, do you agree that
2 diabetes can also be a cause of
3 pancreatic cancer?
4 A. This is --
5 MR. BALL: Objection to
6 form.
7 BY MR. VAUGHN:
8 Q. I'm sorry, can diabetes be a
9 symptom of pancreatic cancer?
10 MR. BALL: Objection to
11 form.
12 THE WITNESS: It is not
13 clear.
14 BY MR. VAUGHN:
15 Q. So the diabetes could
16 potentially be a symptom of pancreatic
17 cancer?
18 A. Well, it's just not clear
19 from the studies.
20 Q. And if it is potentially --
21 if diabetes is potentially a symptom of
22 pancreatic cancer, that would not be
23 proper to consider it a confounder,
24 correct?

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1 MR. BALL: Objection to
2 form.
3 THE WITNESS: So it depends.
4 I mean it depends if it's
5 associated with the symptom or
6 not.
7 MR. VAUGHN: All right. Can
8 we go to Page 34 of his expert
9 report.
10 The top paragraph. I'm
11 sorry.
12 BY MR. VAUGHN:
13 Q. Second one on the right, do
14 you see where you list formaldehyde as a
15 risk factor to pharyngeal cancer?
16 A. It says some -- yeah, it
17 says it's been implicated as risk
18 factors.
19 Q. And you recall earlier we
20 discussed NDMA breaks down into
21 formaldehyde in the body, correct?
22 A. As I said, I didn't
23 understand that reaction. I'm not sure
24 if it's the same form of formaldehyde, if

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1 the --
2 Q. You said that earlier about
3 form of formaldehyde when I was asking
4 about it. What are the different forms
5 of formaldehyde?
6 A. I don't know.
7 Q. Are there different forms of
8 formaldehyde?
9 A. I have no idea.
10 Q. Then why did you say, "I'm
11 not sure it's the same form of
12 formaldehyde"?
13 A. Because I think in that
14 organic chemistry chart you showed me, it
15 was -- formaldehyde was combined with
16 another compound.
17 MR. VAUGHN: Rick, how late
18 do you want to go tonight?
19 THE WITNESS: I'm sorry?
20 MR. BALL: We were talking
21 about going to about 6 o'clock.
22 MR. VAUGHN: You're eastern
23 time?
24 MR. BALL: Yeah.

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1 MR. VAUGHN: How long have
2 we been going since the last
3 break? I haven't been paying
4 attention. I'm sorry. Do you
5 know?
6 THE VIDEOGRAPHER: It's
7 48 minutes.
8 MR. VAUGHN: Say, Rick, you
9 mind -- I know it's been not very
10 long again, but if we take a
11 break, I might be able to not push
12 us too late into the evening
13 before -- see if I can get done
14 before tomorrow.
15 MR. BALL: Okay. That's
16 fine. That's great.
17 MR. VAUGHN: Appreciate it.
18 MR. BALL: We'd all be happy
19 with that.
20 MR. VAUGHN: That's what I
21 figured.
22 THE VIDEOGRAPHER: Off the
23 record, 4:14.
24 (Short break.)

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1 THE VIDEOGRAPHER: We are
2 back on the record at 4:23 p.m.
3 BY MR. VAUGHN:
4 Q. Doctor, have you ever had
5 any conversations with Dr. Anton
6 Pottegard?
7 A. No. I've seen him speak at
8 a lecture before, but that's all.
9 Q. Do you know any of his
10 colleagues that published with him?
11 A. No. I can't -- they're not
12 at Aarhus. I did most of my work at
13 Aarhus. They're at a different
14 university. I think they're at Aalborg
15 or something.
16 Q. Yeah, I think they're at
17 different universities. That's why I was
18 asking. I didn't know if you even knew
19 them.
20 A. Yeah, no.
21 MR. VAUGHN: Tyler, can we
22 go to Page 45 of his expert report
23 now.
24 BY MR. VAUGHN:

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1 Q. Doctor, you reviewed the
2 study by Hidajat, correct?
3 A. Yes.
4 Q. That's a human study of --
5 occupational study exposure to
6 n-nitrosamines?
7 A. In rubber workers.
8 Q. Is that the first human
9 study you're aware of for NDMA in humans?
10 MR. BALL: Objection to
11 form.
12 THE WITNESS: I guess I
13 don't know when it was -- I don't
14 know when it was published. There
15 have been a number of studies of
16 rubber workers.
17 BY MR. VAUGHN:
18 Q. It was published in 2019.
19 A. I'm sure the other ones were
20 prior to that. But I don't know.
21 Q. Do you know if the other
22 ones are actually looking at levels of
23 NDMA that the humans were exposed to?
24 A. I can't recall. I didn't do

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1 a literature search on those.
2 Q. Why did you not do a
3 literature search on those?
4 A. Because the occupational
5 exposure to rubber workers had too many
6 co-exposures, exposures to other things.
7 So it's hard to tease out the NDMA in
8 those workers. So it's not really
9 meaningful.
10 Q. The authors obviously
11 thought it was meaningful to publish the
12 paper, correct?
13 MR. BALL: Objection to
14 form.
15 THE WITNESS: I don't -- I
16 don't know how meaningful they
17 were. I mean, it's some
18 information on rubber workers,
19 absolutely.
20 BY MR. VAUGHN:
21 Q. And whoever peer-reviewed it
22 thought it was legitimate enough to allow
23 it to be published, correct?
24 MR. BALL: Objection to

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1 form.
2 THE WITNESS: Oh, I don't --
3 what journal was it --
4 BY MR. VAUGHN:
5 Q. Well, it got published?
6 A. What journal was it
7 published in? I don't know the review
8 policies or what journal it was in.
9 Q. Did you check what journal
10 it was in when you were reviewing the
11 article?
12 A. I don't recall.
13 Q. Are there some journals that
14 don't do peer review?
15 A. Well, that's one thing I
16 would look for, so I don't know.
17 Q. What journal are you
18 familiar with that doesn't do a
19 peer-review process before allowing an
20 article to be published?
21 A. All the journals I publish
22 in do a peer-review process.
23 Q. Are you aware of any journal
24 that doesn't do a peer-review process?

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1 A. There's something called
2 predatory journals, mostly online-type
3 journals. They just want you to pay to
4 publish your article.
5 Q. International Agency for
6 Research on Cancer, it looks like they
7 made a decision on NDMA in 1978; is that
8 right?
9 A. That's correct. I think
10 they updated it in '92 or something like
11 that.
12 Q. At the bottom of that first
13 paragraph, it notes that, "NDMA should be
14 regarded for practical purposes as if it
15 were carcinogenic to humans." Correct?
16 A. That's what it says, yes.
17 But it doesn't say it is carcinogenic to
18 humans.
19 Q. And this conclusion was
20 before Hidajat came out, correct?
21 A. Correct.
22 MR. VAUGHN: Can we go to
23 the next page, Tyler.
24 THE WITNESS: The Hidajat

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1 came out in 2019. If it had a
2 meaningful impact on their
3 decision, they would have updated
4 it.
5 BY MR. VAUGHN:
6 Q. What do you base that on?
7 A. My knowledge of people that
8 have been at IARC.
9 Q. How quickly does IARC have a
10 turnaround on classifying things as a
11 carcinogens?
12 A. It depends on the strength
13 of the studies that they find. So if it
14 was a concern they would -- they would
15 make an effort to review it.
16 Q. Have any of the people that
17 you've worked with at your various
18 companies been on the -- been employed by
19 IARC?
20 A. Yes.
21 Q. Who?
22 A. Elisabete Weiderpass, the
23 director of IARC, the head of IARC, she
24 worked with me at Karolinska Institutet

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1 in Scandinavia.
2 Q. Anyone else?
3 A. I don't recall anyone else.
4 Q. Have you ever worked for a
5 company that has lobbied IARC for any
6 purpose?
7 MR. BALL: Objection to
8 form.
9 THE WITNESS: Not -- not to
10 my knowledge. I have no idea.
11 BY MR. VAUGHN:
12 Q. Let me see. World Health
13 Organization. It looks like their
14 determination was in 2002, correct?
15 A. No, these are two
16 scientists. They represented the World
17 Health Organization, International
18 Program on Chemical Safety.
19 MR. VAUGHN: And let's go to
20 the next page where it continues
21 talking about these two authors.
22 The second paragraph starts
23 with "however." Can you blow that
24 up.

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1 BY MR. VAUGHN:
2 Q. And can you read that aloud,
3 Doctor?
4 A. "However, because of
5 evidence in animal studies and the
6 similarity of NDMA metabolism in humans
7 and other species, NDMA was held to be
8 highly likely, by the authors of the
9 CICAD, to be carcinogenic to humans. No
10 evaluation of NEDA was conducted."
11 Q. Is that a typo, it should be
12 NDEA?
13 A. Yeah, you're right. You're
14 right. It's NDEA.
15 Q. And so this determination
16 was in 2002, and again that was before
17 the Hidajat study, correct?
18 A. Right. They determined
19 there was not evidence to show that it
20 was carcinogenic to humans.
21 Q. Then U.S. EPA, was there a
22 determination in 1987 on the very bottom
23 there, under A, the third line, is that
24 what that 1987 is referring to?

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1 Sorry --
2 A. It's the Weight of Evidence
3 guidelines, it's how these guidelines in
4 Group A, Group B, Group C. That's what
5 the 1987 refers to.
6 MR. VAUGHN: I'm sorry,
7 Tyler, when I said A, I mean the
8 little A at the bottom, not
9 Group A. I was unclear.
10 THE WITNESS: But it's all
11 mixed in. And in 2021 is their
12 assessment of NDMA.
13 BY MR. VAUGHN:
14 Q. They did an assessment in
15 2021 of NDMA?
16 A. That's when this was taken,
17 absolutely.
18 Q. But did they actually look
19 at NDMA in 2021?
20 A. I'm trying to read my paper.
21 Let me look -- I'll look at my copy here.
22 No, it looks like 1987.
23 Q. Okay. And in 1987, the
24 United States Environmental Protection

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1 Agency classified NDMA as a probable
2 human carcinogen, correct?
3 A. Right, a Group B2. B2, I'm
4 sorry. Group B2.
5 Q. And this determination was
6 made before the Hidajat study in humans,
7 correct?
8 A. Correct.
9 MR. VAUGHN: Can we go to
10 the next page please, Tyler.
11 BY MR. VAUGHN:
12 Q. National Toxicology Program.
13 And if we go down to A on NDMA. Was
14 there a determination made in 2016?
15 A. Yes.
16 Q. And was there a
17 determination that NDMA was reasonably
18 anticipated to be a human carcinogen
19 based on sufficient evidence of
20 carcinogenicity from studies in
21 experimental animals?
22 A. Yes. But it does not say
23 it's carcinogenic to humans.
24 Q. And this was two thousand

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1 --
2 A. You have to be careful of
3 that.
4 Q. And this was 2016. So,
5 again, it was before the 2019 study in
6 humans that Hidajat did, correct?
7 A. Which is interesting to me,
8 because the Hidajat study didn't really
9 move the needle on any of these
10 evaluations, so...
11 Q. Do you have any evidence
12 that any of the agencies that we have
13 went over have reevaluated NDMA?
14 A. I -- the evidence I have is
15 they haven't felt a need to, otherwise
16 they would have published it.
17 Q. So would you agree with me
18 that none of these agencies have
19 reevaluated NDMA?
20 MR. BALL: Objection to
21 form.
22 THE WITNESS: Yeah, they
23 haven't -- they I haven't seen a
24 need to. They haven't done that.

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1 Absolutely.
2 BY MR. VAUGHN:
3 Q. And at the bottom it says
4 Agency For Toxic Substances and Disease
5 Registry.
6 MR. VAUGHN: And if you go
7 to the next page, on 49, Tyler,
8 where it actually has the text.
9 THE WITNESS: Mm-hmm.
10 BY MR. VAUGHN:
11 Q. So in 1989 is when they made
12 their determination on NDMA, correct?
13 A. Correct.
14 Q. They said, "Although there
15 are no reports of NDMA causing cancer in
16 humans, it is reasonable to expect that
17 exposure to NDMA by eating, drinking, or
18 breathing could cause cancer in humans,"
19 correct?
20 A. Correct. It doesn't say it
21 causes, says it's reasonable to expect,
22 which is a different thing.
23 Q. And again, this was in 1989,
24 well before Hidajat's study in humans

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1 showing NDMA increases the risk of
2 cancer, correct?
3 MR. BALL: Objection to
4 form.
5 THE WITNESS: Correct.
6 BY MR. VAUGHN:
7 Q. We have U.S. FDA next.
8 A. Mm-hmm.
9 Q. Is there a reason why a few
10 of these paragraphs are a different
11 color, they are gray instead of black?
12 A. Oh, I see. No, I don't
13 think there's a reason at all.
14 Q. Okay.
15 A. It might be just how it's
16 printed out. Actually it's on there too.
17 Yeah, I don't recall if there is a
18 reason.
19 Q. Do you recall earlier not
20 remembering the FDA's risk assessment for
21 NDMA?
22 A. Correct.
23 Q. Okay. And if you look at
24 the B, the gray paragraph there. Do you

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1 see where it does talk about the FDA's
2 risk assessment?
3 A. Yeah.
4 I just want you to be
5 mindful, this risk assessment, it's
6 really a toxicology activity. It's not
7 an epidemiology activity. So it's really
8 outside the scope of what I do.
9 Q. So you would disagree with
10 the FDA that there would be an increased
11 risk of cancer?
12 MR. BALL: Objection to
13 form.
14 THE WITNESS: The FDA what
15 they -- they say there's one
16 additional case of cancer over the
17 lifetime of 8,000 people, if they
18 were taking the highest valsartan
19 dose possible, 320 milligrams, so
20 I don't agree or disagree with
21 that.
22 BY MR. VAUGHN:
23 Q. Do you know what the highest
24 levels were in valsartan?

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1 A. Wasn't 320 the highest
2 level? I believe it was.
3 Q. I believe 320 is the
4 milligram of the valsartan pill.
5 A. Yes.
6 Q. As far as the NDMA level in
7 valsartan, do you have any idea what the
8 levels are?
9 A. No.
10 Q. So you don't know what the
11 FDA -- what they think the levels are,
12 you don't know if that's accurate or not,
13 do you?
14 MR. BALL: Objection to
15 form.
16 THE WITNESS: I don't. I
17 hope it's accurate.
18 BY MR. VAUGHN:
19 Q. Okay. You would --
20 A. They are making a -- it's a
21 regulatory agency. They are making a
22 decision.
23 Q. If the levels were actually
24 higher than the FDA was aware of, the

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1 cancer risk would be even higher as well,
2 correct?
3 MR. BALL: Objection to
4 form.
5 THE WITNESS: If it's -- if
6 it's higher than what the FDA,
7 you'd think they -- their
8 calculation is wrong, you should
9 inform them.
10 BY MR. VAUGHN:
11 Q. Do you know how the FDA
12 picked out which valsartan pills to test?
13 MR. BALL: Objection to
14 form.
15 THE WITNESS: I have no
16 idea. Again, this is a toxicology
17 activity. It's not epidemiology,
18 so...
19 BY MR. VAUGHN:
20 Q. You have no idea --
21 A. It's beyond the scope of
22 what I do.
23 Q. You have no idea if the --
24 A. It's not --

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1 Q. Sorry. You done? I didn't
2 mean to interrupt you.
3 A. Yeah, I'm sorry, go ahead.
4 Q. So you're not aware if the
5 companies cherry-picked what valsartan to
6 send to the FDA to test, are you?
7 MR. BALL: Objection to
8 form.
9 THE WITNESS: I have no idea
10 if they cherry-picked or didn't
11 cherry-pick or how they got the
12 valsartan pills. It's outside the
13 scope of what I do.
14 MR. VAUGHN: Can we go to
15 the next page, Tyler.
16 BY MR. VAUGHN:
17 Q. You see at the top where it
18 says 96 nanograms a day is what the FDA
19 set the -- set the interim limits to.
20 Are you aware of that?
21 A. That's what it says.
22 Q. And they believed even
23 96 nanograms a day will increase the risk
24 of cancer over 70 years though, correct?

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1 MR. BALL: Objection to
2 form.
3 THE WITNESS: In -- in one
4 out of 8,000 people, isn't that
5 what they said? It's not in
6 everybody.
7 BY MR. VAUGHN:
8 Q. Do you know if that
9 96 nanograms includes --
10 A. I'm sorry, 18 -- no, it's
11 one out of 8,000 people, and NDEA is one
12 out of 18,000 people.
13 Q. Are you aware if these
14 levels, these nanograms per day, include
15 the exposure that humans get through
16 their diet?
17 A. I assume it's exposure in
18 the diet, endogenous exposure, et cetera.
19 MR. VAUGHN: Go to Page 51,
20 Tyler.
21 And 124. If we go about
22 two-thirds of the way down on the
23 right-hand side, it starts with
24 "air measures." Yeah.

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1 BY MR. VAUGHN:
2 Q. Can you read that sentence
3 aloud for us, Doctor?
4 A. "Air" -- I'm sorry. Let me
5 look here. "Air measures of NDMA may not
6 accurately reflect the dose a worker
7 experiences because a portion of what is
8 inhaled is then exhaled."
9 Q. So does that mean that the
10 workers in Hidajat were actually exposed
11 to less NDMA?
12 MR. BALL: Objection to
13 form.
14 THE WITNESS: We're not --
15 we're not clear about what levels
16 people at Hidajat were exposed to.
17 It's not only this issue, but it's
18 also the issue dealing with the
19 exposure estimates from 1 year in
20 1967, and took that to be
21 exposures over the whole lifetime
22 of the people between '67 and
23 2015.
24 So there's a lot of issues

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1 with Hidajat.
2 BY MR. VAUGHN:
3 Q. Would you agree that part of
4 the NDMA they were exposed to would have
5 been exhaled?
6 MR. BALL: Objection.
7 THE WITNESS: Yes.
8 BY MR. VAUGHN:
9 Q. I'm sorry. I couldn't hear
10 you over that objection.
11 A. I'm sorry.
12 Q. Let me ask the question
13 again.
14 A. I'm talking too fast.
15 Q. No, you're fine.
16 Would you agree that part of
17 the NDMA that the workers in Hidajat were
18 exposed to would have been exhaled?
19 A. Okay. And what was your
20 question?
21 Q. That was my question. Would
22 you agree that part of the NDMA that the
23 workers in Hidajat were exposed to would
24 have been exhaled?

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1 A. That's what I wrote, yes.
2 MR. VAUGHN: Can we go to
3 the next page, please. Yeah, that
4 first -- yeah.
5 BY MR. VAUGHN:
6 Q. Can you read the last
7 sentence aloud for us, Doctor?
8 A. It is absurd to suggest that
9 workers in this study had similar levels
10 of exposure to NDMA as valsartan users
11 and that any findings of this study are
12 applicable.
13 Q. Doctor, what were the NDMA
14 levels in valsartan?
15 A. So that, I don't know. The
16 workers in Hidajat were breathing in
17 NDMA. And valsartan you take orally. So
18 it's a different exposure route.
19 Q. Why does that matter?
20 A. Because carcinogens act
21 differently depending on how they are
22 taken, how they're, you know, taken into
23 the body.
24 Q. And how is NDMA going to act

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1 differently if it's inhaled versus taken
2 orally?
3 A. That, we don't know. But
4 it's not the same exposure.
5 Q. Would different organs be
6 susceptible because it's through air as
7 opposed to oral?
8 A. You know, I have no idea.
9 But it's not the same exposure route.
10 Q. And again, you have no idea
11 of the minimum or the maximum levels of
12 NDMA in any valsartan pills, correct?
13 A. I don't. Or in the Hidajat
14 study, we don't know what the levels are
15 there either.
16 Q. So you don't know the levels
17 in Hidajat. You don't know the levels in
18 valsartan. And you're saying that it's
19 absurd for the plaintiffs' expert to
20 suggest that workers in this study,
21 Hidajat, had similar levels of exposure
22 to NDMA as valsartan users?
23 A. Because it's --
24 Q. If the plaintiffs' experts

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1 do know all of that information, why
2 would it be absurd for them to say that?
3 MR. BALL: Objection to
4 form.
5 THE WITNESS: The route of
6 exposure was different.
7 BY MR. VAUGHN:
8 Q. That's not what your paper
9 says. It doesn't say anything about
10 route of exposure. It just says that the
11 levels -- it would be absurd to suggest
12 that the levels were similar?
13 A. You have to read the whole
14 paragraph though.
15 (Reading to himself.)
16 One thing that you have to
17 try to understand in epidemiology is how
18 representative your population is to the
19 population that you're concerned about.
20 And rubber workers isn't the
21 same as a valsartan user. If you think
22 it is, then you would have to -- you
23 know, you would have to give evidence
24 that it is.

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1 Q. Was Hidajat comparing rubber
2 workers to valsartan users?
3 A. No. But the plaintiffs'
4 experts are.
5 Q. Didn't you previously
6 testify that generally occupational
7 exposures are the mainstay for
8 determining carcinogens?
9 MR. BALL: Objection to
10 form.
11 THE WITNESS: If -- if the
12 carcinogens are taken in a similar
13 manner. You have to -- you have
14 to evaluate them.
15 BY MR. VAUGHN:
16 Q. So like, chromium, air
17 versus water, do you think one of those
18 routes is noncarcinogenic?
19 A. You have to --
20 MR. BALL: Objection to
21 form.
22 THE WITNESS: -- evaluate
23 it.
24 BY MR. VAUGHN:

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1 Q. Say it again.
2 A. You have to evaluate it.
3 They're different exposures.
4 Q. If you're -- if a substance
5 is a carcinogen via one route, isn't it a
6 known carcinogen?
7 MR. BALL: Objection to
8 form.
9 THE WITNESS: I don't know.
10 But the route of exposure is
11 important.
12 BY MR. VAUGHN:
13 Q. Doctor, is it your opinion
14 that all of the NDMA exposure in Hidajat
15 was via the respiratory exposure?
16 MR. BALL: Objection to --
17 sorry. Objection to form.
18 THE WITNESS: I'd have to
19 look at the paper.
20 But, you know, they only
21 used one year of exposure data and
22 applied it over, you know, the
23 whole lifetime of the plant
24 workers, the rubber plant workers.

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1 But they're assuming that the
2 level of exposure is the same
3 across all the years. But the --
4 BY MR. VAUGHN:
5 Q. Did they not check -- sorry.
6 A. -- personal protective
7 equipment, they don't look for any
8 confounders. Those type of things.
9 Q. Is it your testimony that in
10 Hidajat, they did not determine levels of
11 NDMA exposure every year?
12 A. So they calculated what they
13 considered to be levels, you know, based
14 on the data that they had, which was
15 good. But it may or may not be accurate.
16 They did nothing to show that it was or
17 wasn't accurate. We don't even know if
18 the people worked in the same jobs
19 throughout that whole time period. We
20 just know that they were in the same
21 department. We don't know if the
22 department had the same exposure level
23 throughout it or not.
24 Q. Do you recall critiquing

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1 Dr. Madigan for assuming that the
2 occupational exposure to NDMA was
3 respiratory in Hidajat?
4 A. You'd have to show me what I
5 said.
6 Q. You don't recall?
7 A. There are a lot of things
8 I -- a lot of problems I have with
9 Dr. Madigan.
10 Q. But you don't recall
11 critiquing him for assuming that the
12 occupational exposure in Hidajat to NDMA
13 was respiratory?
14 A. You have to show me where I
15 said that. I don't -- I don't recall.
16 MR. VAUGHN: If you can go
17 to Page 54 of his expert report.
18 Number 135. Two-thirds of the way
19 down.
20 BY MR. VAUGHN:
21 Q. "Dr. Madigan's calculations
22 assumed occupational exposure to NDMA was
23 respiratory."
24 A. Okay.

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1 Q. Do you disagree? You do not
2 think that the NDMA was respiratory in
3 Hidajat?
4 A. No. What I'm saying is that
5 the NDMA exposure in -- for valsartan
6 users wasn't respiratory --
7 Q. That's not what this says --
8 (Simultaneous speaking.)
9 THE COURT REPORTER: Just
10 one second. What?
11 BY MR. VAUGHN:
12 Q. This says --
13 A. The NDMA exposures for
14 valsartan use wasn't respiratory.
15 Q. But that's not what this
16 says, right? This says, "Dr. Madigan's
17 calculations assumed occupational
18 exposure to NDMA was respiratory."
19 A. Right. And so I don't know
20 why you would consider a valsartan user
21 as having respiratory NDMA, and also that
22 it remained constant throughout their
23 career.
24 Q. Do you think that Hidajat

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1 was something besides respiratory
2 exposure to NDMA?
3 A. I don't.
4 MR. VAUGHN: I have no
5 further questions at this time.
6 MR. BALL: Can we take about
7 a ten-minute break, and we'll
8 figure out what we want to do.
9 MR. VAUGHN: What do you
10 mean figure out what you want to
11 do?
12 MR. BALL: Okay. Thank you.
13 We can stay off for about ten
14 minutes.
15 MR. VAUGHN: What do you
16 mean figure out what you want to
17 do?
18 THE WITNESS: Okay.
19 MR. BALL: If I want to do
20 any redirect.
21 MR. VAUGHN: Oh, okay.
22 Gotcha.
23 MR. BALL: Sorry. Sorry if
24 I was unclear. Just give us --

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1 give us ten minutes, okay?
2 MR. VAUGHN: Not a problem.
3 Thank you.
4 THE VIDEOGRAPHER: Off the
5 record, 4:48.
6 (Short break.)
7 THE VIDEOGRAPHER: We are
8 back on the record at 5:00 p.m.
9 MR. BALL: Duane Morris
10 doesn't have any questions for
11 Dr. Fryzek.
12 And I believe -- I don't
13 believe any of the other defense
14 counsel do, but I'll let them
15 speak up for themselves if they
16 feel like they need to.
17 (No response.)
18 MR. BALL: Nope. Okay,
19 we're done.
20 MR. VAUGHN: Thank you for
21 your time, Dr. Fryzek.
22 THE VIDEOGRAPHER: That
23 concludes this deposition.
24 The time is 5:01 p.m.

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1 *****
 2 (Excused.)
 3 (Deposition concluded at
 4 approximately 5:01 p.m.)
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1
 2 CERTIFICATE
 3
 4
 5 I HEREBY CERTIFY that the
 6 witness was duly sworn by me and that the
 7 deposition is a true record of the
 8 testimony given by the witness.
 9
 10 It was requested before
 11 completion of the deposition that the
 12 witness, JON P. FRYZEK, Ph.D., have the
 13 opportunity to read and sign the
 14 deposition transcript.
 15
 16 MICHELLE L. GRAY,
 17 A Registered Professional
 18 Reporter, Certified Shorthand
 19 Reporter, Certified Realtime
 20 Reporter and Notary Public
 21 Dated: October 11, 2021
 22
 23 (The foregoing certification
 24 of this transcript does not apply to any
 reproduction of the same by any means,
 unless under the direct control and/or
 supervision of the certifying reporter.)

Page 452

1 INSTRUCTIONS TO WITNESS
 2
 3 Please read your deposition
 4 over carefully and make any necessary
 5 corrections. You should state the reason
 6 in the appropriate space on the errata
 7 sheet for any corrections that are made.
 8 After doing so, please sign
 9 the errata sheet and date it.
 10 You are signing same subject
 11 to the changes you have noted on the
 12 errata sheet, which will be attached to
 13 your deposition.
 14 It is imperative that you
 15 return the original errata sheet to the
 16 deposing attorney within thirty (30) days
 17 of receipt of the deposition transcript
 18 by you. If you fail to do so, the
 19 deposition transcript may be deemed to be
 20 accurate and may be used in court.
 21
 22
 23
 24

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1 - - - - -
 2 E R R A T A
 3 - - - - -
 4 PAGE LINE CHANGE
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 6 REASON: _____
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 22 REASON: _____
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 24 REASON: _____

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do
hereby certify that I have read the
foregoing pages, 1 - 455, and that the
same is a correct transcription of the
answers given by me to the questions
therein propounded, except for the
corrections or changes in form or
substance, if any, noted in the attached
Errata Sheet.

JON P. FRYZEK, Ph.D. DATE

Subscribed and sworn
to before me this

____ day of _____, 20____.

My commission expires: _____

Notary Public

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LAWYER'S NOTES

PAGE LINE

1	_____	_____	_____
2	_____	_____	_____
3	_____	_____	_____
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ERRATA SHEET

Case Name: Valsartan, Losartan, and Irbesartan Products Liability Litigation (MDL No. 2875)

Deposition Date: September 30, 2021

Deponent: Jon Fryzek

1. To clarify the record
2. To conform to the facts
3. To correct transcription error

Pg.	Line	Now Reads	Should Read	Reason
19	9	415	412	3
78	10	By	Been	3
94	14	Where	why	3
99	5	Used	I used	3
131	19	Conducted	Controlled	3
166	7	I did them	I did use them	3
169	4-5	Notre Dame	Vanderbilt	3
187	8	Written by	Written about	3
189	10	One restriction	One indicative	3
210	5	Take---	Take the data	3
210	13	Do the data	Take the data	1
274	3	The s value	The estimate	3
305	27	Say it would I still find no	Say I would still find no	3
362	12	Studies of the	Studies review by the	3
375- 376	24, 1-3	The way to control by confounding is done by age is having a certain age group.	The way to control confounding by age is to only study a certain age group.	3
376	2-3	Then you are confounding	Then you are controlling	3

Date:

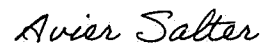
Oct 27, 2021

Signature:


Jon Fryzek (Oct 27, 2021 14:14 EDT)

Seal:

Notary Public Commonwealth of Virginia
Registration No. 7931695
Commission Expire; Jul 31, 2025



Notary

7931695

Registration#

07/31/25

Expiration Date:

ACKNOWLEDGMENT OF DEPONENT

I, Jon Fryzek, do
hereby certify that I have read the
foregoing pages, 1 - 455, and that the
same is a correct transcription of the
answers given by me to the questions
therein propounded, except for the
corrections or changes in form or
substance, if any, noted in the attached
Errata Sheet.

Jon Fryzek
JON P. FRYZEK, Ph.D.

10/27/21

DATE

Subscribed and sworn
to before me this
27th day of October, 2021.
My commission expires: 07/31/25

Avier Salter 7931695

Notary Public

Notary Public Commonwealth of Virginia
Registration No. 7931695
Commission Expires; Jul 31, 2025